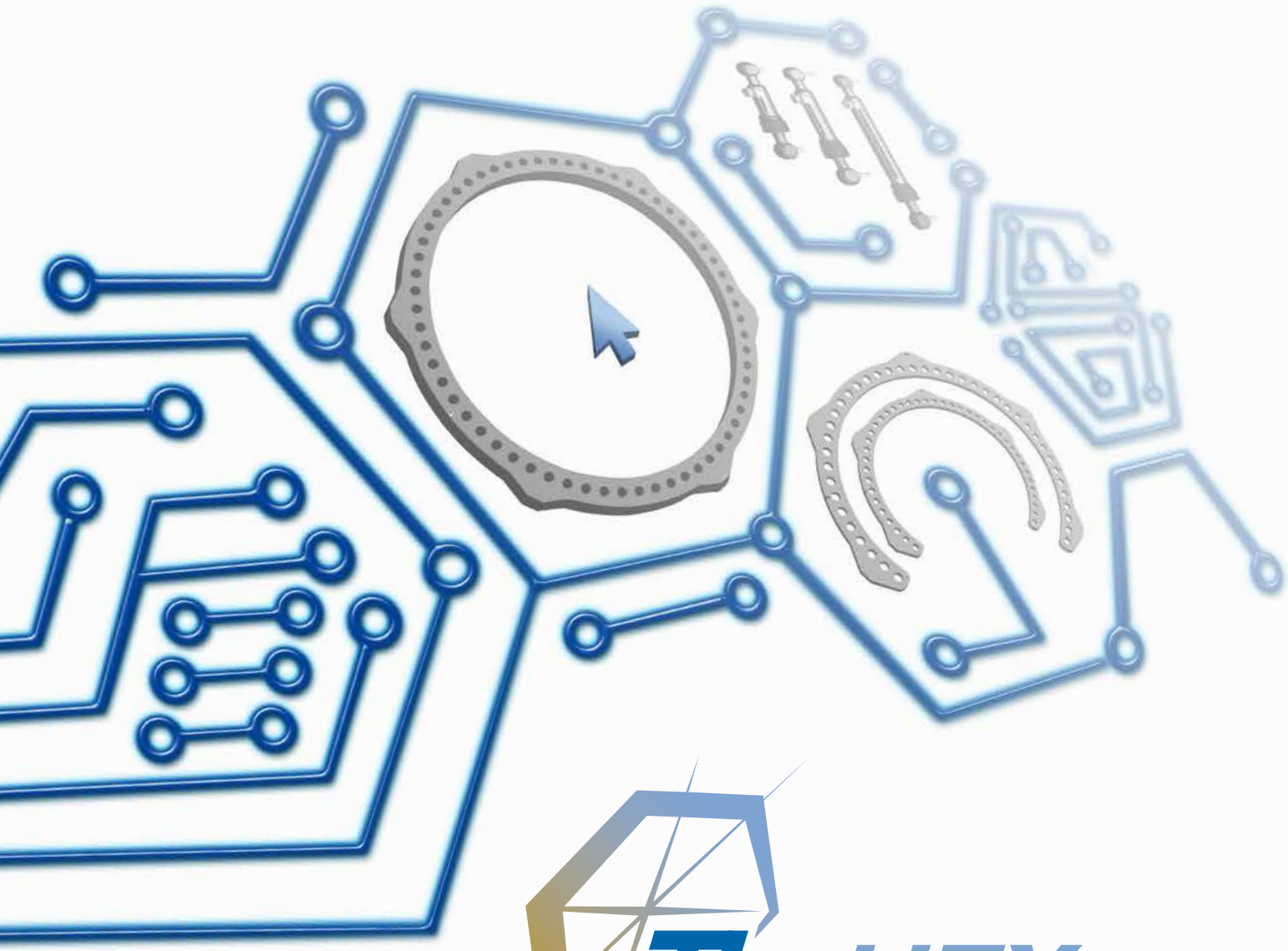

TL-HEX™
TRUELOK HEXAPOD SYSTEM

Software User's Guide

Software Version 1.2

ORTHOFIX®

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Orthofix wishes to thank the following surgeons for their contribution to the development of this User's Guide:

Franz Birkholtz, M.D.
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William Terrell, M.D.

TL-HEX Software User's Guide: Software version 1.2

The applicable End User License Agreement can be found at http://tlhex.com/policies/Eulapolicy.html

The applicable privacy policy can be found at http://tlhex.com/policies/privacypolicy.html

Security Precautions:
User is advised to clear the browser history (temporary Internet files, cookies, etc.) after logging out of the TL-HEX application.

Computer System Requirements

Display Settings:
Screen resolution of 1024 x 768 Pixel or higher.

Supported Browsers:
Microsoft Internet Explorer®: Version 8 or 9

Microsoft and Internet Explorer are either registered trademarks or trademarks of Microsoft Corporation in the United States and/or other countries

Internet Connection:
High-speed Internet connectivity is recommended.

Language Setting:
Select the "Language" setting in the Internet Explorer browser for the country of origin. This will provide the correct date setting.

My Username: _____

My Password: _____

My Email Address: _____

1. Introduction

The TL-HEX is a circular external fixator based on Ilizarov principles. The working segment of this frame consists of a hexapod made up of two rings (circular external supports) and six variable-length struts (Fig.1). The relative strut lengths determine the position of the rings in space. Because the rings are attached to bone segments, their position indirectly determines the position of the bone segments.

The Software is able to calculate strut length adjustments for surgeon's review and approval.

The software needs three sets of parameters to calculate correction. These are:

1) deformity parameters
2) frame parameters
3) mounting parameters

The deformity parameters define to the software what the deformity or fracture displacement looks like. The second set of parameters describes the size and shape of the frame that is used. The third set of parameters designates where the frame's reference point is in relation to the fracture or deformity area. With these sets of parameters the software will be able to calculate, for surgeon review and approval, appropriate strut adjustment for the patient to achieve the treatment goals.

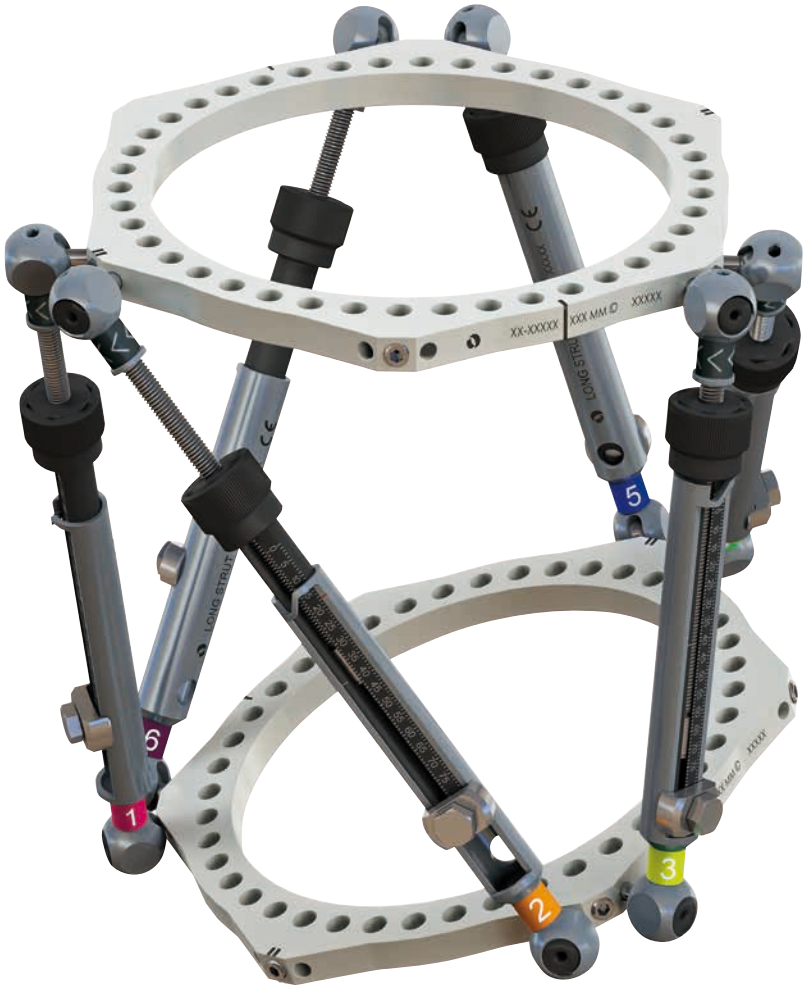


Fig.1 TL-HEX circular external fixator consists of two rings and six variable-length struts.

2. Nomenclature

In the description of the fracture or deformity, one of the bone segments is defined as the ***reference segment*** and the other one as the ***moving segment***. In the software diagrams, the ***reference segment*** is indicated as a ***blue*** segment, and the ***moving (non-reference)*** segment as ***green***. The surgeon chooses a reference segment, either proximal or distal. Choosing proximal reference means that the frame and the deformity are oriented relative to the axis of the proximal segment. The deformity parameters (what the bone looks like) should be described accordingly. Therefore, the translation and rotation of the distal segment is described in relation to the proximal segment. If the distal segment is chosen as the reference segment, the frame and the deformity are orientated relative to the axis of the distal segment and measurements would need to be taken in relation to this orientation. For example, medial translation of the distal bone segment would be described as lateral translation because the proximal segment would be translating laterally in relation to the distal (reference) segment (Fig. 2).

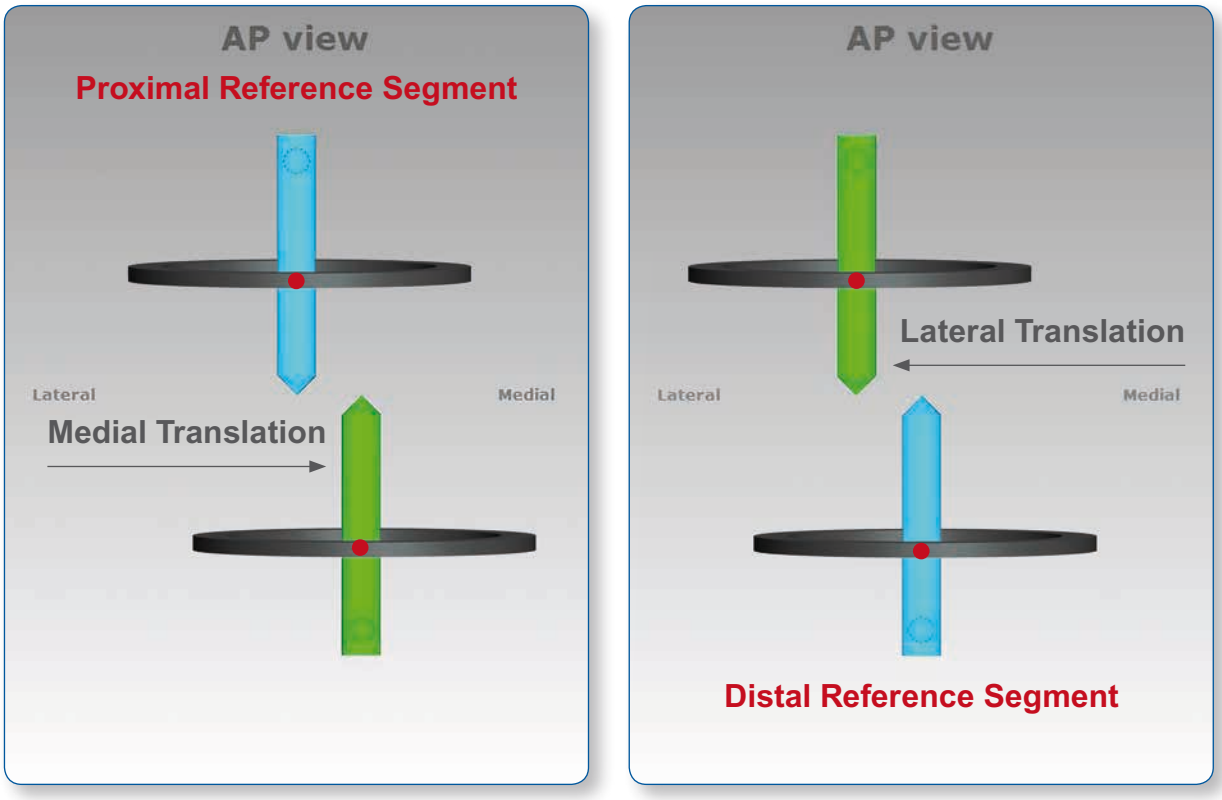


Fig. 2. Description of moving bone segment translation depending on proximal or distal location of the reference segment.

It is important to realize that changing from proximal to distal referencing will change direction of translation in both AP and ML views and the direction of rotation in the Axial view, but will not change length or angulation parameters because these are mathematically independent of the point of reference.

To minimize measurement errors on the x-rays, the shortest segment should be used as a reference segment. For example, if a correction was performed around a proximal tibial osteotomy or fracture, the proximal segment should be used for referencing. If surgeon is dealing with a distal femoral fracture or deformity, the distal segment should be used as the reference segment.

There are three diagrams in the software. The first diagram is the **AP view** diagram corresponding to the standard AP x-ray of the limb. The second diagram is the **ML view** diagram representing the standard ML x-ray of the limb. There are orientation keys on these two diagrams that indicate the medial/lateral and anterior/posterior aspects, respectively. The third diagram is the **Axial view** diagram representing the view we would have when looking either up or down the limb from the reference segment. On this diagram, the orientation keys are anterior, posterior, medial, and lateral (Fig. 3).

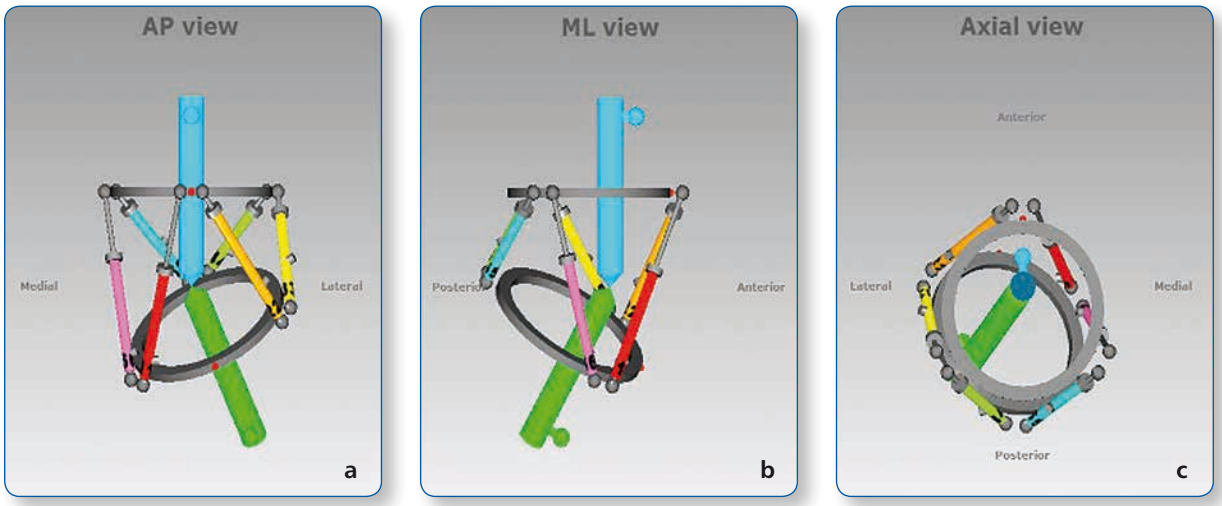


Fig. 3. Standard **AP view** (a), **ML view** (b) and **Axial view** (c) software diagrams. The proximal (reference) segment is indicated in **blue** and the distal (moving) segment in **green**. There is valgus-procurvatum deformity of the limb as evidenced by the direction of angulation on the AP view. The frame is comprised of two rings interconnected by 6 struts. In all three diagrams, the master and antimaster tabs are marked with **red dots**.

The struts are attached to full rings or 5/8 rings in pairs using special angulated tabs around the circumference of the external support. Each full ring has 3 working tabs, which will have struts attached to them and three non-working tabs. Each 5/8 ring has 3 working and 2 non-working tabs. For proper identification, the struts are numbered using color number clips. The clips are numbered from 1 to 6 and color coded as **red** (1), **orange** (2), **yellow** (3), **green** (4), **blue** (5), and **purple** (6).

The struts are numbered by the surgeon, according to the following rules:

- On the proximal external support, struts 1&2, 3&4, and 5&6 will be strut pairs that run on the three common working tabs
- On the distal external support, struts 2&3, 4&5, and 6&1 will converge onto the common working tabs
- The tab from which strut 1 and 2 originate is hence always on the proximal ring and is known as the **master tab**
- The master tab is important to determine the way that the frame is rotated around the limb when referencing proximally
- The tab on the distal ring that is situated opposite to the master tab (i.e., the one in the base of the triangle formed by struts 1 and 2) is called the antimaster tab
- The antimaster tab is important to determine the way that the frame is rotated around the limb when referencing distally
- The master tab is always on the proximal ring and the antimaster tab is always on the distal ring, regardless of which segment is chosen as the reference segment

- 5/8 Rings open medially
  - For a 5/8th ring open medially on the proximal reference limb segment, with no rotational defect, the master is the nearest angulated end tab that is anti-clockwise from the anterior point of the limb. The anti-clockwise rotation is for both right and left limbs.
  - The master tab rotation is always anti-clockwise, which means for the left limb there is an "external" rotation value and for the right limb there is an "internal" rotation value.
- The rotational values are automatically calculated

The software will create a *prescription,* for surgeon review and approval, indicating direction and daily amount of adjustment for each strut. TL-HEX struts (Fig. 4) consist of two telescoping aluminum tubes, an outer tube (A) and an inner tube (B), which can be locked together at various lengths using the side locking bolt (C) and clamp washer (D). The inner tube is attached to a spring-loaded, black knurled adjustment knob (E). The adjustment knob mates with the threaded rod (F) in a manner such that the rod translates relative to the inner tube when the knob is rotated. This will provide gradual changes of overall strut length in 0.5-mm increments. Each strut has two special joints (G,H), one at the base of the outer tube (tube end joint) and the other at the end of the threaded rod (rod end joint). Each joint has a mounting stud (I, J), which can be inserted into the mounting holes on the ring tabs and held in place by the locking screw.

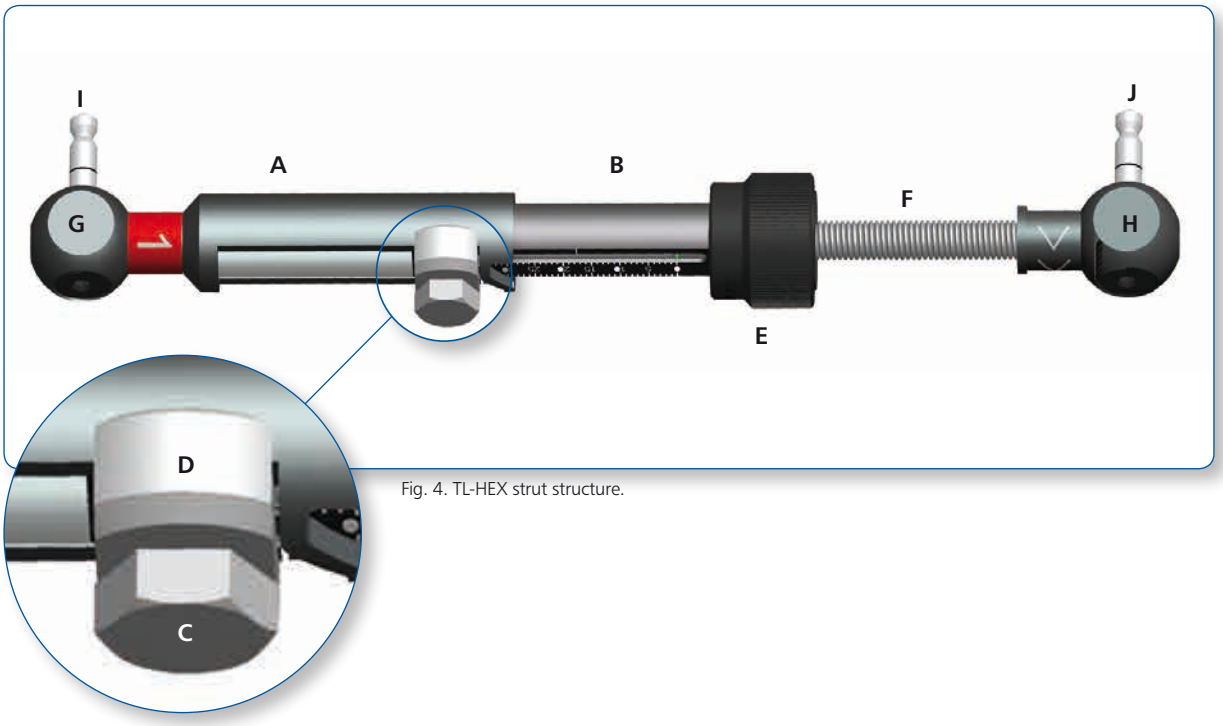


Fig. 4. TL-HEX strut structure.

The TL-HEX struts allow performing *acute and gradual adjustment*. The acute adjustment of the strut length is achieved by untightening the side locking bolt, sliding the inner tube relative to the outer tube to the desired length and re-tightening the locking bolt. Acute adjustment is indicated by the inner tube scale in 1-mm increments relative to the orange-line mark on the outer tube (Fig.5 a). The gradual adjustment is achieved by pulling and rotating the adjustment knob resulting in a noticeable detent (tactile click) every 0.5 mm of adjustment. Gradual adjustment is indicated by the same scale relative to the green-line mark on the end of the threaded rod (Fig.5 b). The direction of adjustment is indicated by the direction clips. The arrow of the direction clips is oriented according to the prescription (see details in General Principles of TL-HEX Frame Assembly, TL-1201-OPT-E0).

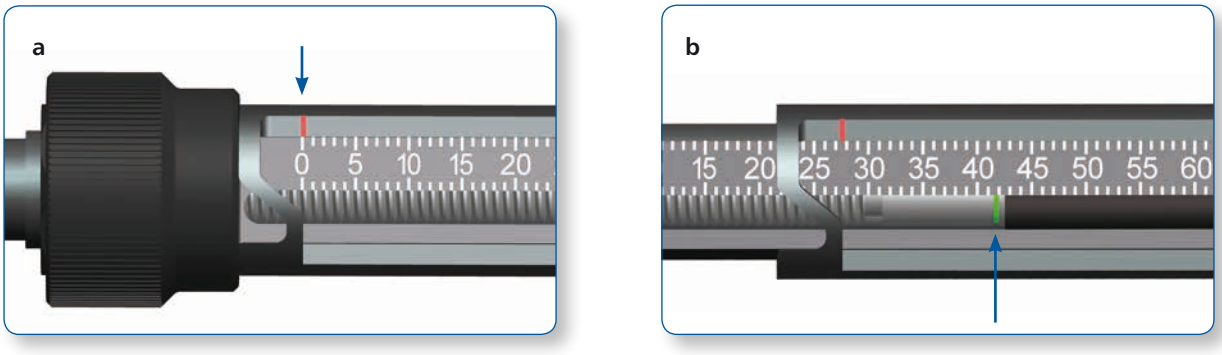


Fig. 5. Indicators for acute (a) and gradual (b) adjustments on the TL-HEX struts.

3. User Access and Account Management

3.1 Obtaining Access

Access to the TL-HEX software is controlled by an Username and Password. The username and password can be obtained at www.tlhex.com by requesting a new account from the Home Page and following the onscreen instructions. Upon a request being received by Orthofix, it will be validated to confirm whether the applicant has undergone the necessary training to use the system safely and responsibly. Once approved, the surgeon's user account will be activated, and Username and Password will be emailed to the applicant.

3.2 Login Screen

The TL-HEX application is located at: http://app.tlhex.com. This location provides the Login screen (Fig. 6). Enter a valid Username and Password in the appropriate text fields, and click **Sign In** to gain access to the software.

Click "Forgot your Username or Password?" link to retrieve username or to reset the password.

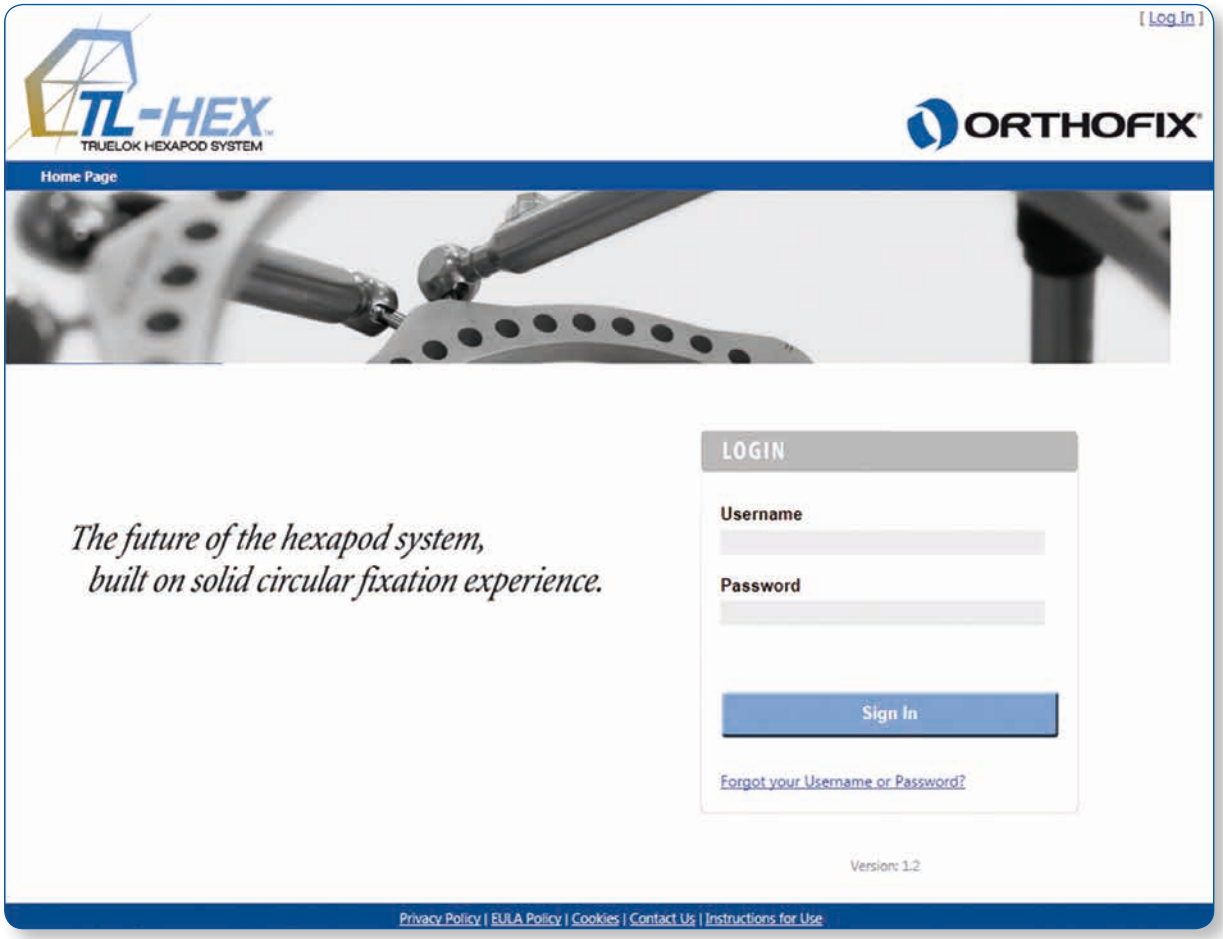


Fig. 6. TL-HEX software Login screen.

To reset the password, user is asked to provide the username in the relevant field and click **Reset Password**.
A new password is generated and sent by email.

To retrieve or restore the username, user needs to contact directly the TL-HEX Customer Care.

3.3 Home Page

After a successful login, the user enters the Home Page of TL-HEX software (Fig. 7).

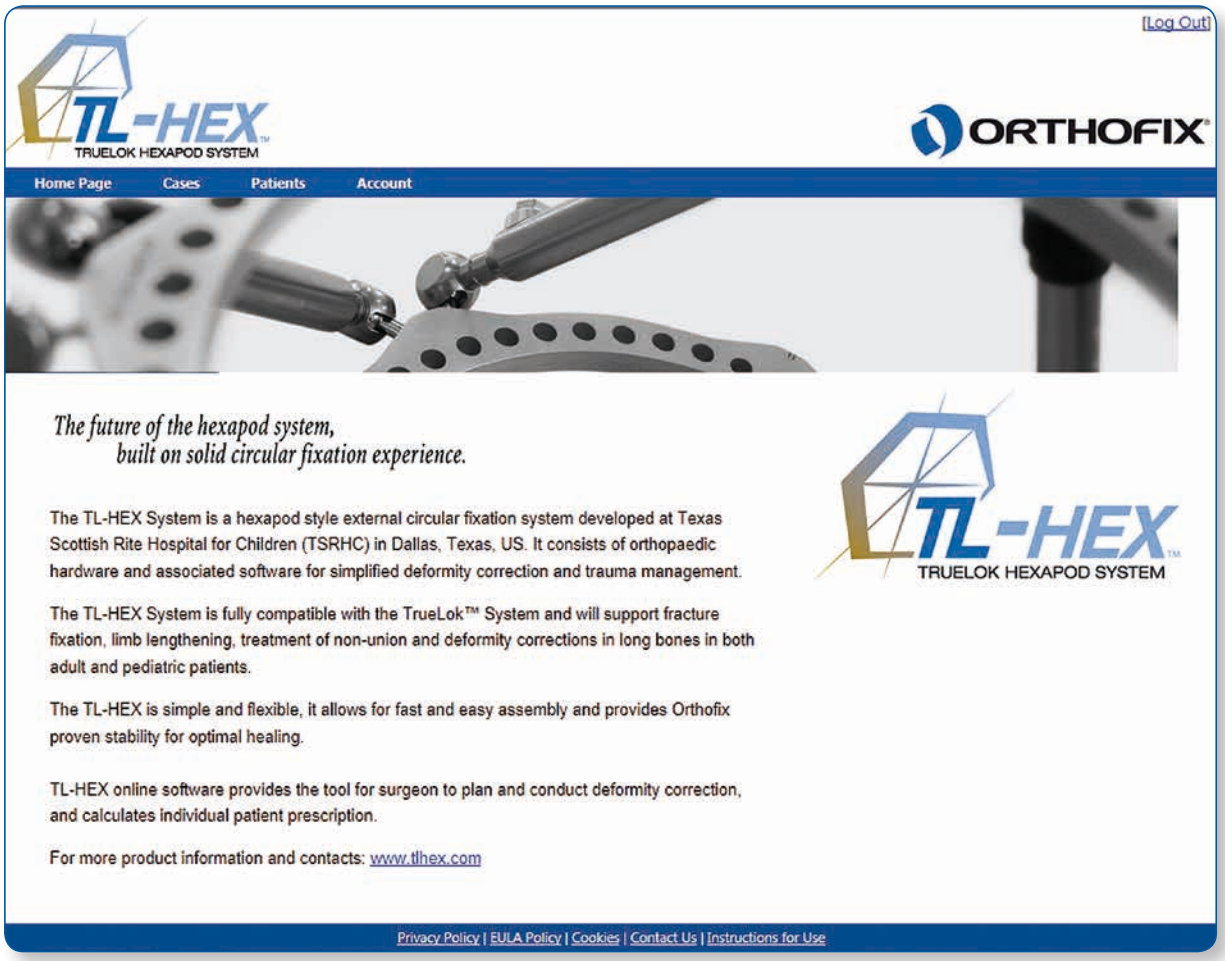
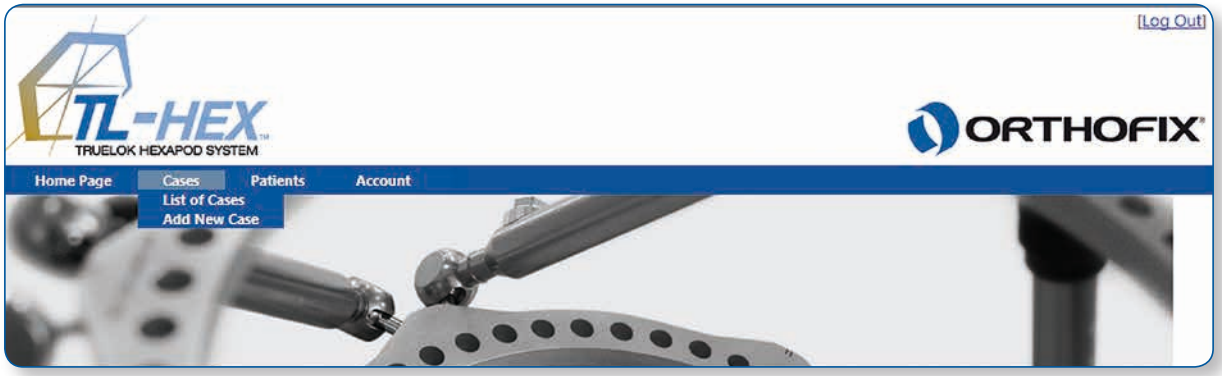


Fig. 7. TL-HEX software Home Page.

4. Patient and Case Management

4.1 Menu Structure

Patients and **Cases** menus include a list of patients or cases and allow the surgeon to add a new patient or case, respectively. All cases are related to a patient (Fig. 8). Therefore, a new patient must be created prior to beginning a new case. There are no restrictions on the number of cases that can be associated with each patient.



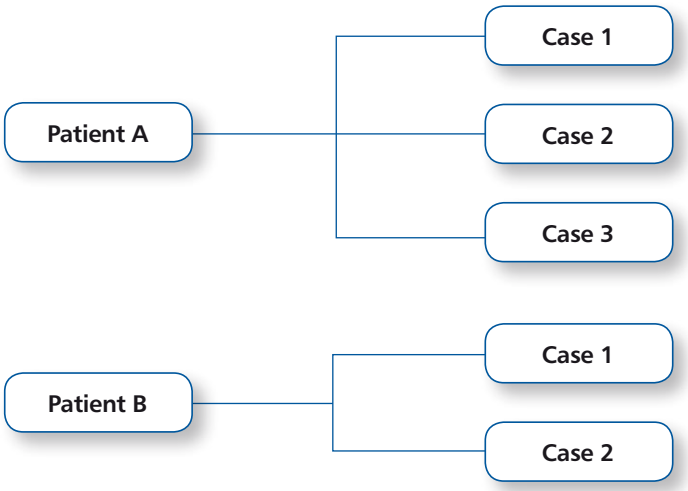


Fig. 8. Patient and Case management menus and structure.

4.2 Add a New Patient

Patients → Add New Patient

All patients are entered into the system through the **Add New Patient** menu. For each new patient (Fig. 9), surgeon should assign a Patient ID, insert Patient Initials (or other reference associated with this patient), select patient Gender, followed by clicking on **Save Patient** . This will open the list of patients, which will include all previously entered patients as well as the newly created patient.

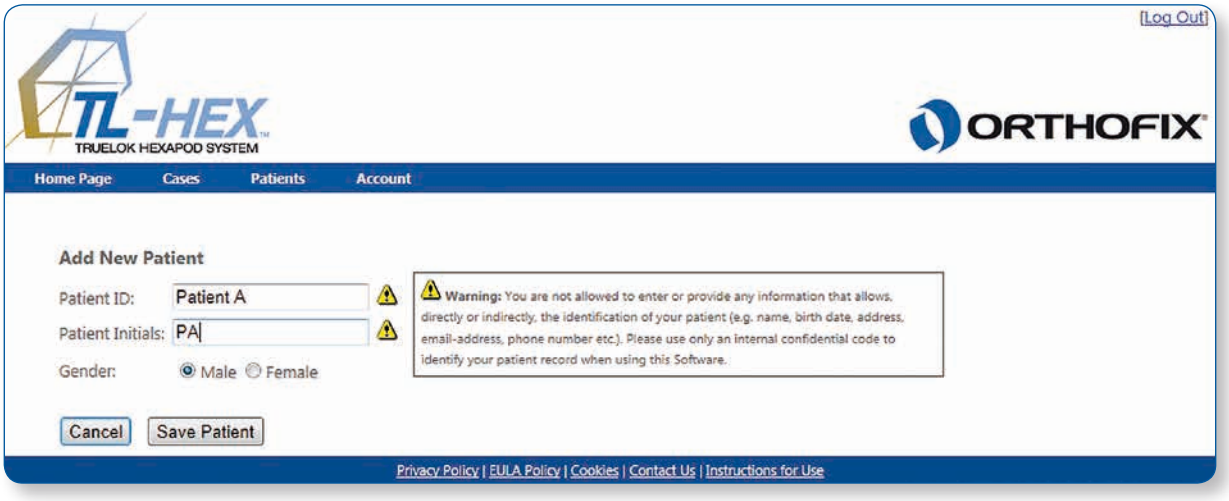


Fig. 9. Add New Patient screen.

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

4.3 List of Patients

Patients → List of Patients

User can also view all of the patients by clicking **List of Patients**. This option appears as the cursor hovers over the Patients field of the Navigation menu. From this list (Fig. 10), the surgeon can select a patient, which will be lead to the list of cases associated with this patient.

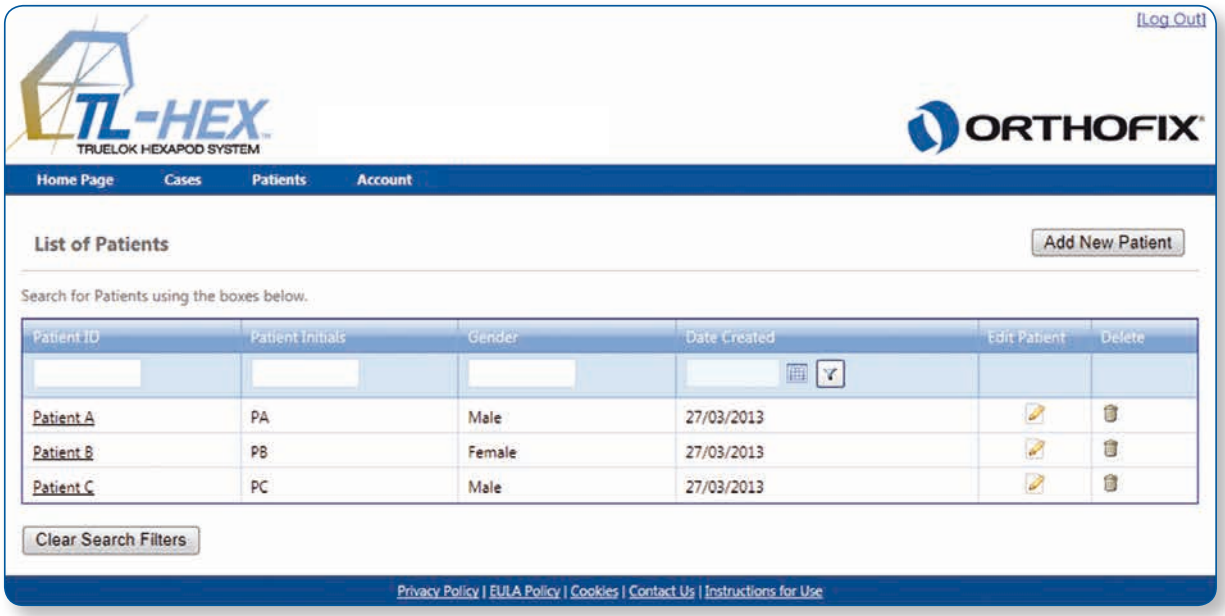


Fig. 10. List of Patients screen.

Use the box related to each header to filter and search the content based on a specified criteria.
To filter or search within a column (Patient ID, Patient Initials, Gender, Date Created), insert the search criteria in the relevant box and press Enter.

Note that for Date Created header it is possibile to set complex filter using the available function, by clicking the .

To remove any filter, click the button Clear Search Filters.

The List of Patients can be also sorted by clicking on any of the headers (i.e., Patient ID, Patient Initials, Gender and Date Created) in the table (Fig. 10).

4.4 New Case

Cases → Add New Case

Cases menu includes two options: **List of Cases** and **Add New Case.** A new case can be added by selecting **Add New Case** from the **Cases** menu. Alternatively, surgeon can add a new case by clicking Add New Case in the **List of Cases**. Note that all cases must be associated with a patient. When creating a new case, the patient is selected from the drop-down selector sorted by Patient ID, to the right of Patient ID label. If no patients have been entered, the drop-down selector will be empty.

Note: A patient must be created before a case can be created.

For each new case (Fig. 11), the surgeon should assign a Case Number and a Case Name (reference associated with this case). Select gender, left/right side and the planning date, followed by entering Notes associated with this case (optional).

Proceed to the next step in the treatment planning process by clicking Next .

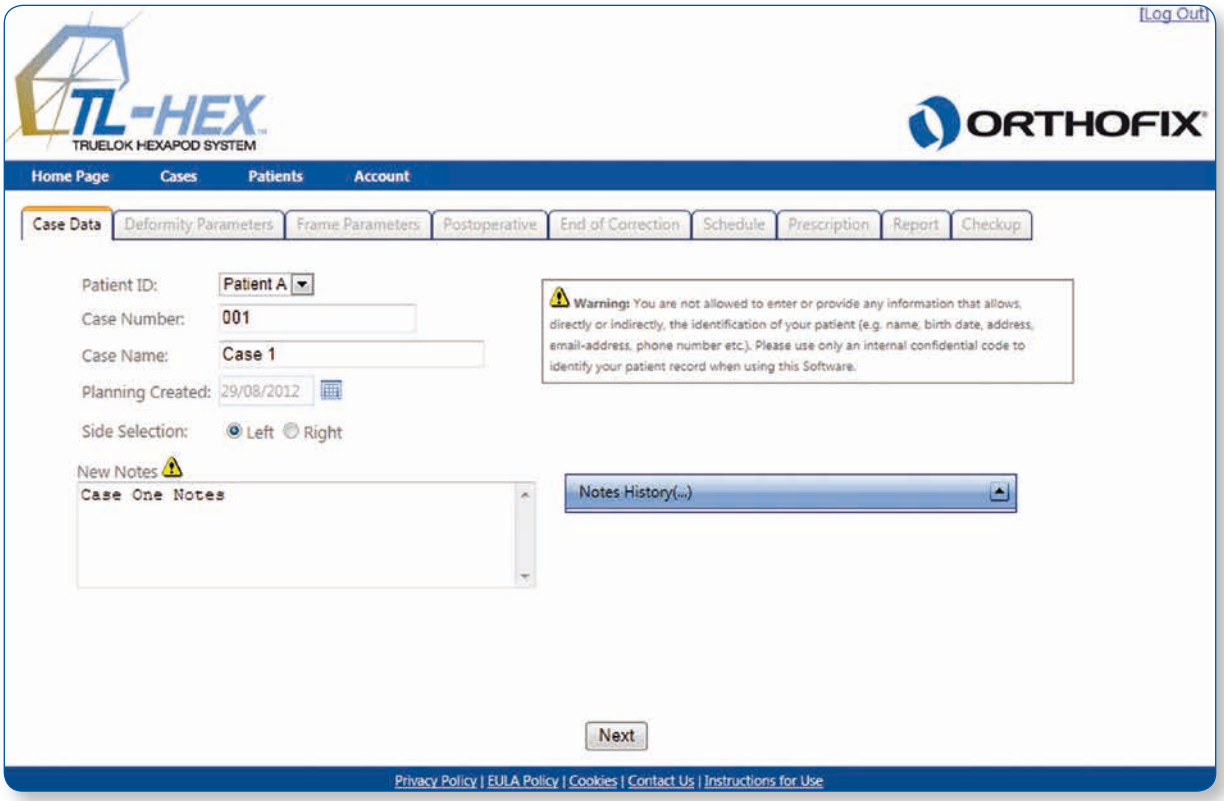


Fig. 11. Add New Case screen.

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

4.5 View Cases

Cases → List of Cases

All cases for all patients in the **List of Cases** are sorted by the Patient ID. The List of Cases can be also sorted by clicking on any of the headers (i.e., Case Number, Case Name, Anatomy, Date Created) in the table (Fig. 12).

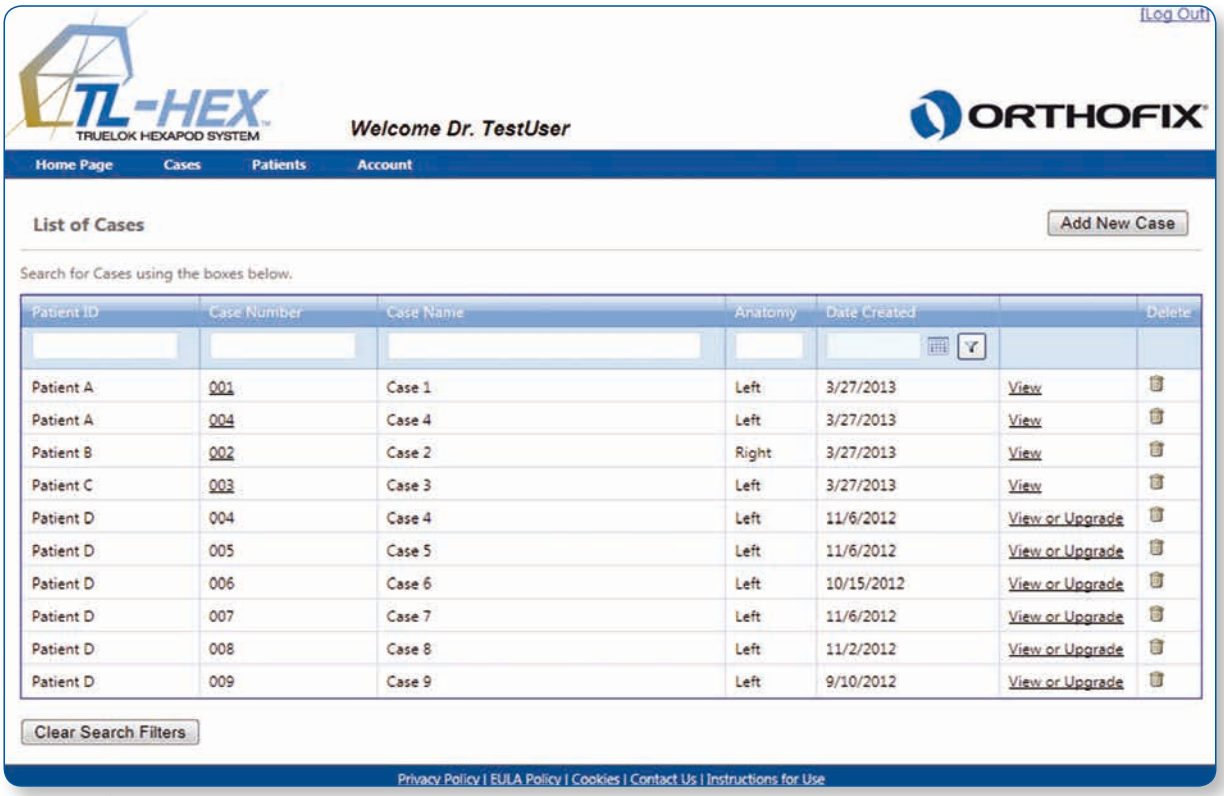


Fig. 12. List of Cases screen.

As per the List of Patients, use the box related to each header to filter and search the content based on a specified criteria. To filter or search within a column (Patient ID, Case Number, Case Name, Anatomy, Date Created), insert the search criteria in the relevant box and press Enter.

Note that for Date Created header, it is possibile to set a complex filter using the available function, by clicking th .

To remove any filter, click the button Clear Search Filters .

The List of Cases can be also sorted by clicking on any of the headers (i.e., Case Number, Case Name, Anatomy, Date Created) in the table (Fig. 12).

Upgrade from version 1.1 to 1.2

Case Version Management

When a new case is created, the current software version (1.2) will be used. The cases created with Software version 1.2 have an additional link "View" that allows a read-only version of the case to be displayed.

If the case was created with the older software version (1.1), the additional link field will be "VIEW OR UPGRADE". Once clicked on "View or Upgrade", a read-only page is presented with the following warning message and an "Upgrade Case" button.

Warning message: "You are attempting to open a Case that was created on an earlier software version. By clicking the Upgrade button you can upgrade the case to the new version. All the data will be transferred to a new case. It is recommended that you review and confirm all of the data because the prescription will be recalculated".

This "Upgrade Case" button generates a new case using the old case input data. The new case must be checked since prescription data may change in the upgrade. The new case will be named "Upgrade-Of_<cases name>".

The older version of the case is still retained in a read-only mode.

5. Case Planning

5.1 Case Data

Case data includes Patient ID, case number, case name (reference associated with this case), anatomical site (left or right), and date of planning (see 4.4 New Case for details).

5.2 Deformity Parameters

Once the case information is entered, click **Next** to move to the Deformity Parameters screen to enter parameters associated with the deformity (Fig. 13).

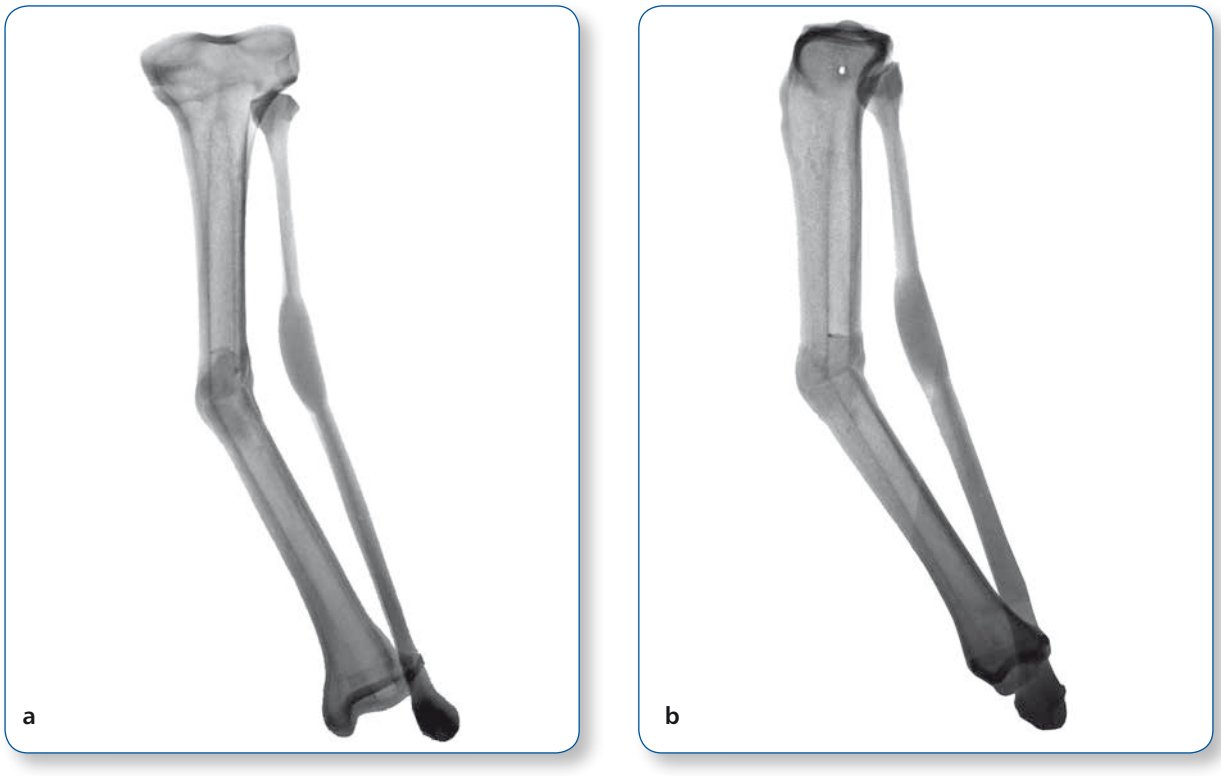


Fig.13. AP view (a) and ML view (b) radiographs of oblique plane midshaft tibial deformity (valgus - procurvatum).

The first step is to choose the reference segment (Fig. 14). The surgeon is free to choose either the *proximal* or *distal segment* as the reference segment depending on the clinical scenario (see 2. Nomenclature for details).

Fig.14. Default Deformity Parameters screen.

Deformity description includes 3 angulations and 3 translations (Fig. 14). The three angulations are coronal plane angulation in **AP view**, sagittal plane angulation in **ML view** and horizontal plane angulation (rotation) in **Axial view**. *Coronal plane angulation* can be either varus or valgus, depending whether the distal segment is bent towards or away from the midline, respectively. *Sagittal plane angulation* will be described as either apex anterior (procurvatum) or apex posterior (recurvatum). *Horizontal plane angulation* can be described as internal or external rotation. With internal rotation, for example, the distal segment is rotated along its longitudinal axis towards the midline. Because the rotation is difficult to measure radiologically, this parameter will be most commonly established clinically. All angulations are described in degrees. Their direction is independent regardless of whether proximal or distal referencing is chosen.

Similarly, the three possible segment translations are described in the **AP view** *(coronal plane)*, **ML view** *(sagittal plane)* and **Axial view**. In the *coronal plane*, the translation can be medial or lateral. Medial translation, for example, means that the moving segment is translated medially relative to the reference segment. In the *sagittal plane*, the translation can be anterior or posterior. Note that these two translations are described in millimeters in relation to the reference segment and direction of translations will change depending on whether proximal or distal referencing is used (see 2. Nomenclature for details).

The third type of translation occurs along the longitudinal axis of the limb. In the software, the *axial translation* is described in millimeters as short or long. The first option (short) is used when the moving bone segment is translated (compressed) towards the reference bone segment. When the moving bone segments is translated (distracted) away from the reference bone segment, the second option (long) is used in description of the axial translation (Fig. 15).

In addition, the *bone length* is included in description of the axial translation. Again, the software provides two options to indicate whether the bone is short or long and enter the relevant amount of bone length discrepancy in millimeters.

Note: The bone length is a clinical parameter indicating limb length discrepancy relative to contralateral limb and will not change bone segment orientation in the software diagrams.

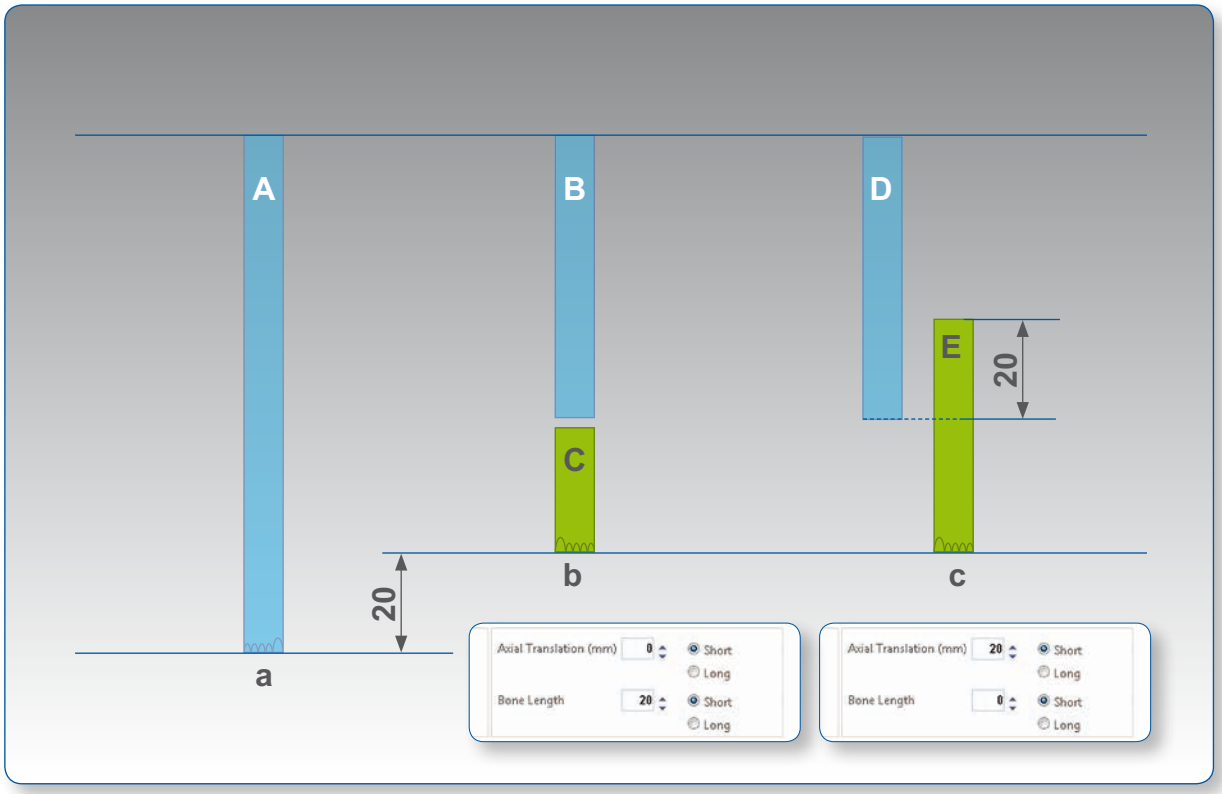


Fig. 15. Description of translation along the longitudinal axis and bone length: (a), contralateral (normal) limb; (b), short limb as result of bone shortening without axial translation; (c), short limb due to axial translation of bone segments. Note that the combined length of bone segments B and C is shorter than the length of contralateral bone segment A. The combined length of segments D and E, however, is equal to the length of contralateral bone segment A.

Click **Update Views** at any time to refresh the display according to the parameters entered (Fig. 16).

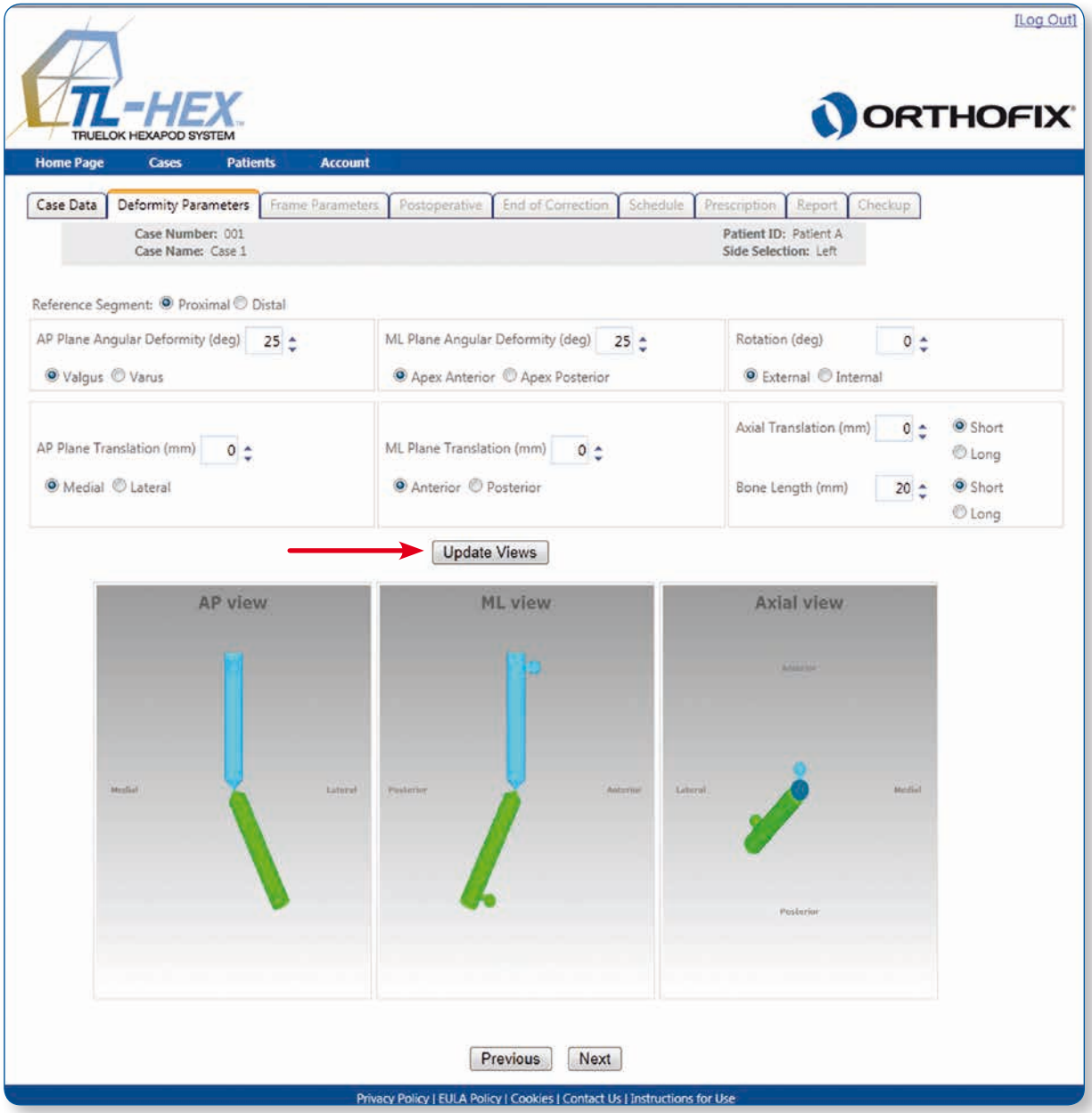


Fig. 16. Updated Deformity Parameters screen.

Note: It is an important safety mechanism to check whether the diagrams on the software correspond to the deformity that is seen on the patient's x-rays and/or clinically. Click **Update Views** after any changes or updates to deformity parameters.

Once satisfied with the deformity parameters that have been entered, click either the Frame Parameters tab or **Next** to proceed to the Frame Parameters screen.

5.3 Frame Parameters and Mounting Parameters

Frame Parameters screen (Fig. 17) includes two sections: **Select External Supports** and **Preoperative Mounting Parameters**. Select External Supports section consists of two drop-down menus (ring type and ring size) for each of the proximal and distal external supports. In the example shown, 180 mm full rings have been selected. Should an open external support be chosen (i.e., a 5/8 ring), the relevant ring orientation (open posteriorly, open medially, open anteriorly) should be selected from the drop-down menu. The software will automatically change the orientation offset of the 5/8 ring in the Frame Rotation field with the relevant read-only value. This value can be overridden in the Postoperative Screen.

Note: If choosing two 5/8 rings, the openings cannot be oriented in the same direction (e.g., both open anteriorly, posteriorly, medially). The Software also does not allow 5/8 ring placement open laterally. Surgeon can adjust orientation of 5/8 rings later in the Postoperative screen, placing their openings in desired orientation by entering rotation of the reference ring and postoperative struts lengths (but the openings in the same directions, as well laterally will still be not permitted by the software).

Fig. 17. Frame Parameters screen.

Preoperative Mounting Parameters section appears underneath the external support selection drop-down menus. The default assumption is that both proximal and distal external supports are perpendicular to the corresponding bone segment axis and located at 50 mm distance from the apex of the deformity or the osteotomy/fracture level. The screen provides the capability of adjusting the position of the reference ring in the coronal plane (AP translation) sagittal plane (ML translation) relative to the reference bone segment axis. In addition, the reference and moving ring positions can be adjusted in the axial direction relative to the apex of deformity or the osteotomy/fracture level, in the Reference Ring box.

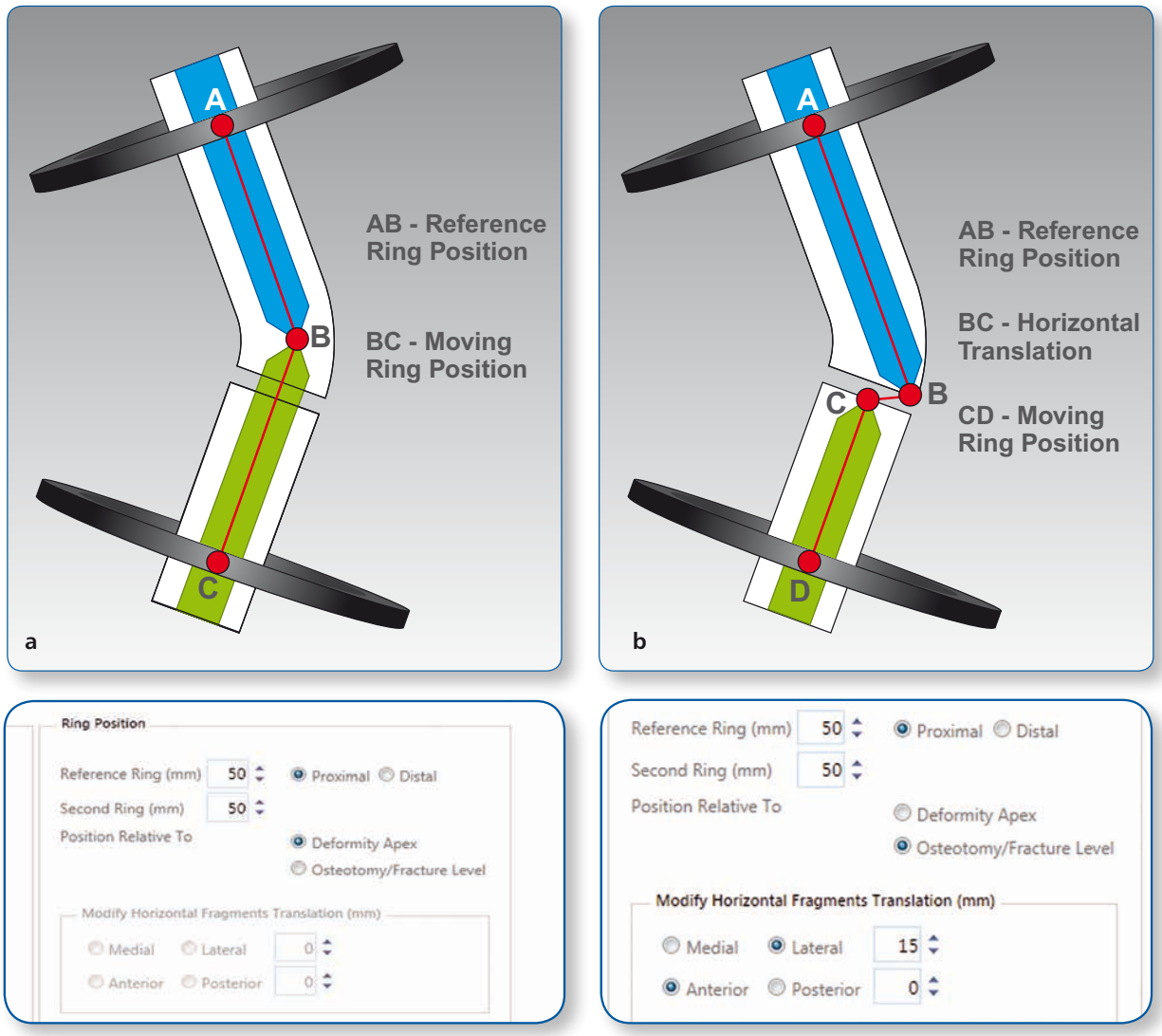


Fig. 18. Description of Reference Ring Box relative to deformity apex (a) or osteotomy/fracture level (b).

In the Reference Ring box, the reference ring position in the coronal and the sagittal planes is described in millimeters as the translation (medial/lateral and anterior/posterior, respectively) of the center of the reference ring in relation to the longitudinal axis of the reference bone segment. While in the Reference Ring Box, the reference ring position along the longitudinal axis of the reference bone segment (proximal/distal) is described in millimeters as a distance from the center of the reference ring to the specific point of interest. Similarly, the position of the second ring is described in millimeters as a distance from the same point of interest.

Either the apex of the deformity or the level of the osteotomy/fracture can be chosen as point of interest (Fig. 18).
If the AP or ML translation was entered into the deformity parameters section, the osteotomy/fracture level is automatically chosen as point of interest. The surgeon has the ability to adjust previously entered horizontal segment translation depending on the distance between the point of interest and deformity apex.

Although the surgeon can skip entering the mounting parameters, it is suggested that the surgeon completes the Preoperative Mounting Parameters section. This simplifies the overall data entry and then the application suggests the appropriate strut type and length.

Mounting Parameters section allows preassembly of the frame before surgery to mimic the patient's deformity. Clicking the Update Views button after entering the mounting parameters will reveal the preassembled frame construct and render a set of strut lengths that will result in the required frame (Fig. 19).

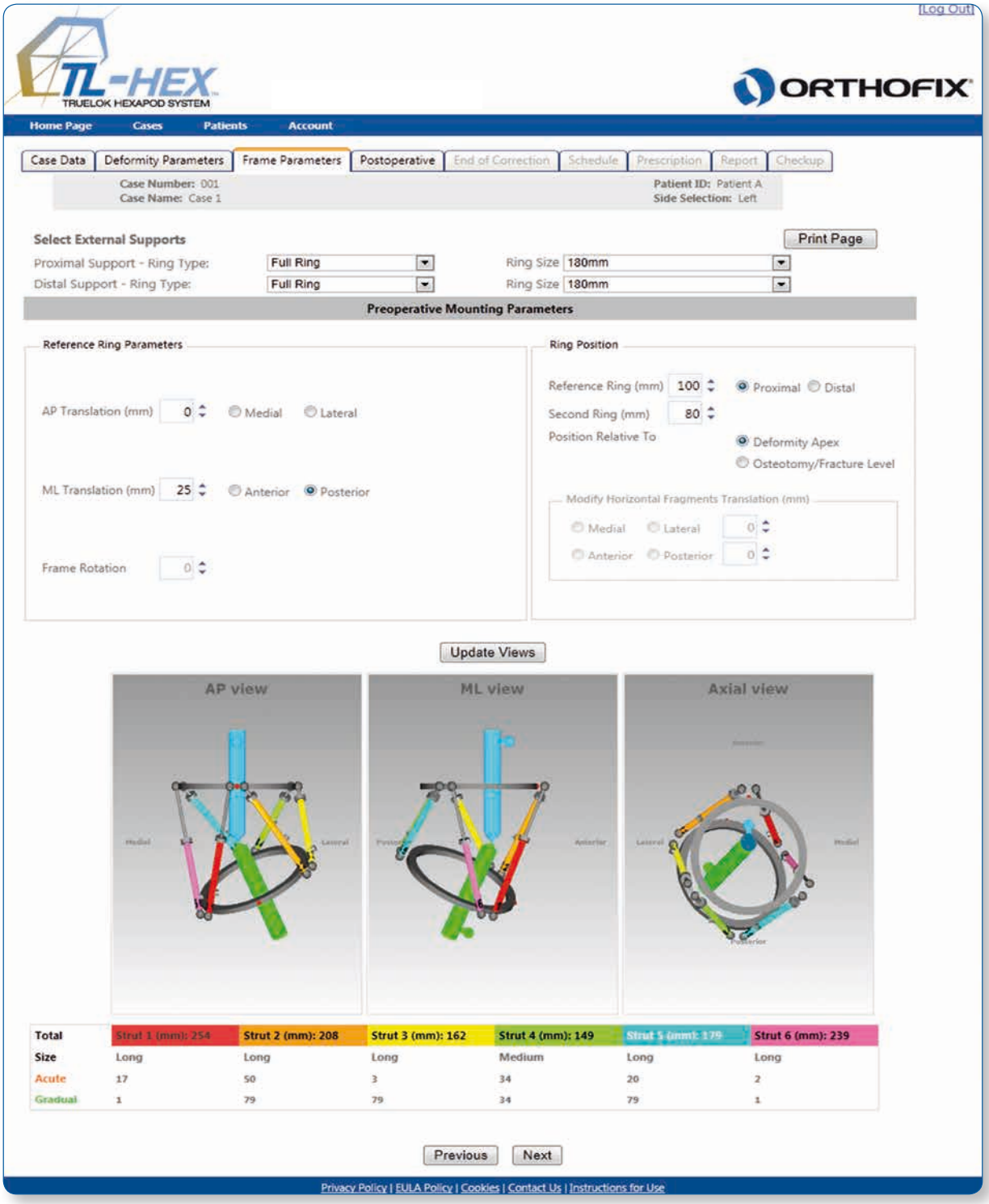


Fig. 19. Updated Frame Parameters screen.

After clicking "Update Views", check the bottom of the screen for struts that are out of range (indicated by a red number). An out of range strut can be addressed by modifying the mounting parameters of the Frame Parameters screen or the surgeon may proceed to Postoperative screen.

The complete planning can be printed by clicking the **Print Page** button. The summary of the planning can be printed by clicking **Print Frame Parameters**.The hard copy of the planning can be inserted into the patient's chart for the record. It can also be used to request appropriate frame components, as well as to preassemble the frame. Mounting Parameters portion of frame parameters can be skipped if the surgeon doesn't want to pre-build a frame or doesn't have the possibility to do a pre-plan of the surgery; in this case he can proceed directly to Postoperative screen.

Fig. 20. Frame Parameters Print view screen.

Note: Although the surgeon can skip entering the mounting parameters, it is suggested that the surgeon complete the Mounting Parameters section. This simplifies the overall data entry and then the application suggests the appropriate strut type and length.

5.4 Postoperative Assessment

The Postoperative screen (Fig. 21) provides the ability to enter two sets of parameters (including frame mounting parameters and strut lengths) according to the postoperative position of the rings and struts.

Fig. 21. Postoperative screen.

In the top portion of the Postoperative screen, the position of the reference ring relative to the reference bone segment is entered. Similarly to the Frame Parameters screen in the Reference Ring Parameters box, reference ring translation in coronal (medial/lateral) and sagittal (anterior/posterior) planes is described in millimeters as translation of the center of the reference ring in relation to the longitudinal axis of the reference bone segment.

Three (not present in the Mounting Parameters screen section) reference ring angulation parameters are added to the Postoperative screen. These parameters reflect angular deviation of the reference ring orientation in the coronal (**AP view**), sagittal (**ML view**) and horizontal (**axial view**) planes from the orthogonal position relative to the reference bone segment. On the AP view, the reference ring angulation is described in degrees as an angle between the projection of the ring and the axis of bone segment with the medial side of the ring either up or down. On the ML view, the reference ring angulation is described in degrees as an angle between the projection of the ring and the axis of bone segment with the anterior side of the ring either up or down. On the axial view, the reference ring angulation (rotation) is described in degrees as external or internal rotation relative to the longitudinal axis of the reference bone segment. If proximal referencing was chosen, the master tab will determine the rotational frame offset. If distal referencing was chosen, the antimaster tab will determine the rotational frame offset (Fig. 22).

In the axial plane, translation of the reference ring (proximal/distal) along the longitudinal axis of the reference bone segment is described in millimeters as a distance from the center of the reference ring to specific point of interest (deformity apex or osteotomy/fracture level).

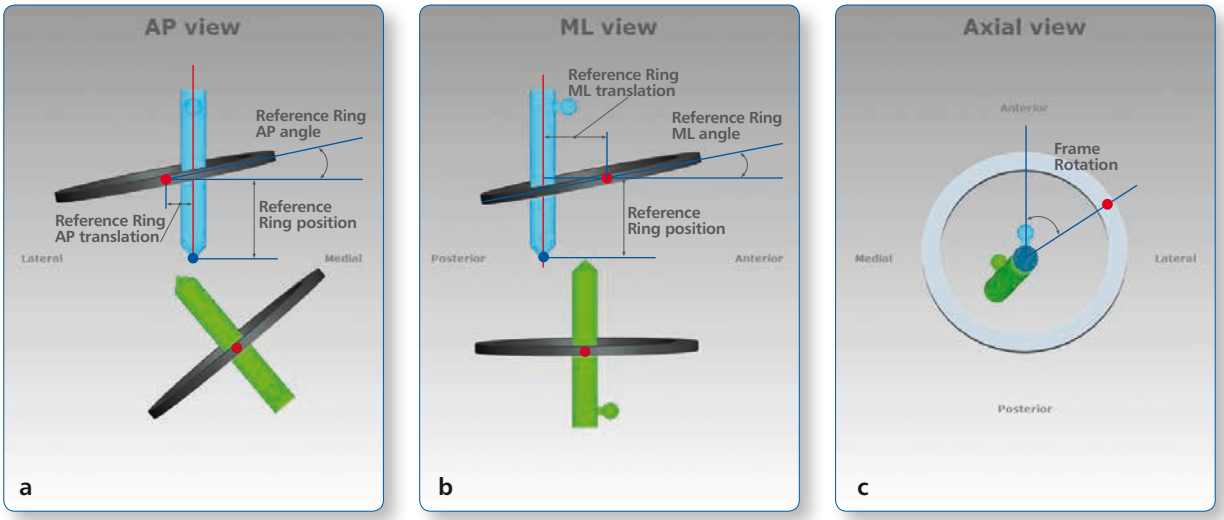


Fig. 22. Reference ring angulation, translation and rotation parameters in AP view (a), ML view (b) and Axial view (c).

At the bottom of the screen (Fig. 21), the strut mounting parameters are entered for all six struts. Parameters for each strut are described in three fields. The first field indicates the strut size (e.g. short, medium, long). The second field is the acute length for the strut in millimeters, which is read off the scale relative to the acute length orange mark. The third field is the gradual length for the strut in millimeters, which is read off the same scale relative to the gradual length green mark. Note that the strut types/lengths in conjunction with the previously entered deformity parameters will define the position of the second (moving) ring relative to the moving bone segment.

If preoperative planning was performed previously, all data (including frame mounting parameters and strut lengths) is transferred automatically to the corresponding fields of the Postoperative screen. The Surgeon should confirm the data or adjust it if necessary. Strut type (short, medium and long) as well as both acute and gradual adjustment lengths recorded at the end of the surgery should be confirmed or adjusted in the corresponding fields.

These adjustments will describe not only the final shape and orientation of the frame, but also where it is located in relation to the bone segments. Clicking on the **Update Views** at this point will render software generated diagrammatic models that reflect the bone deformity and frame position on the x-rays. In case of discrepancy, the surgeon should go back and check all the variables before proceeding to the next step.

If changes are made in the Postoperative screen followed by changes to deformity parameters, frame parameters section should be skipped over assuming that the frame is already placed on the patient and the surgeon is just modifying deformity parameters or frame position relative to reference bone segment.

In the software, the strut length entries are validated against the type (size) of struts selected. If the entered value exceeded the range for any given strut, an error is indicated and the strut size/length should be corrected prior to proceeding to the next step (Fig. 23).

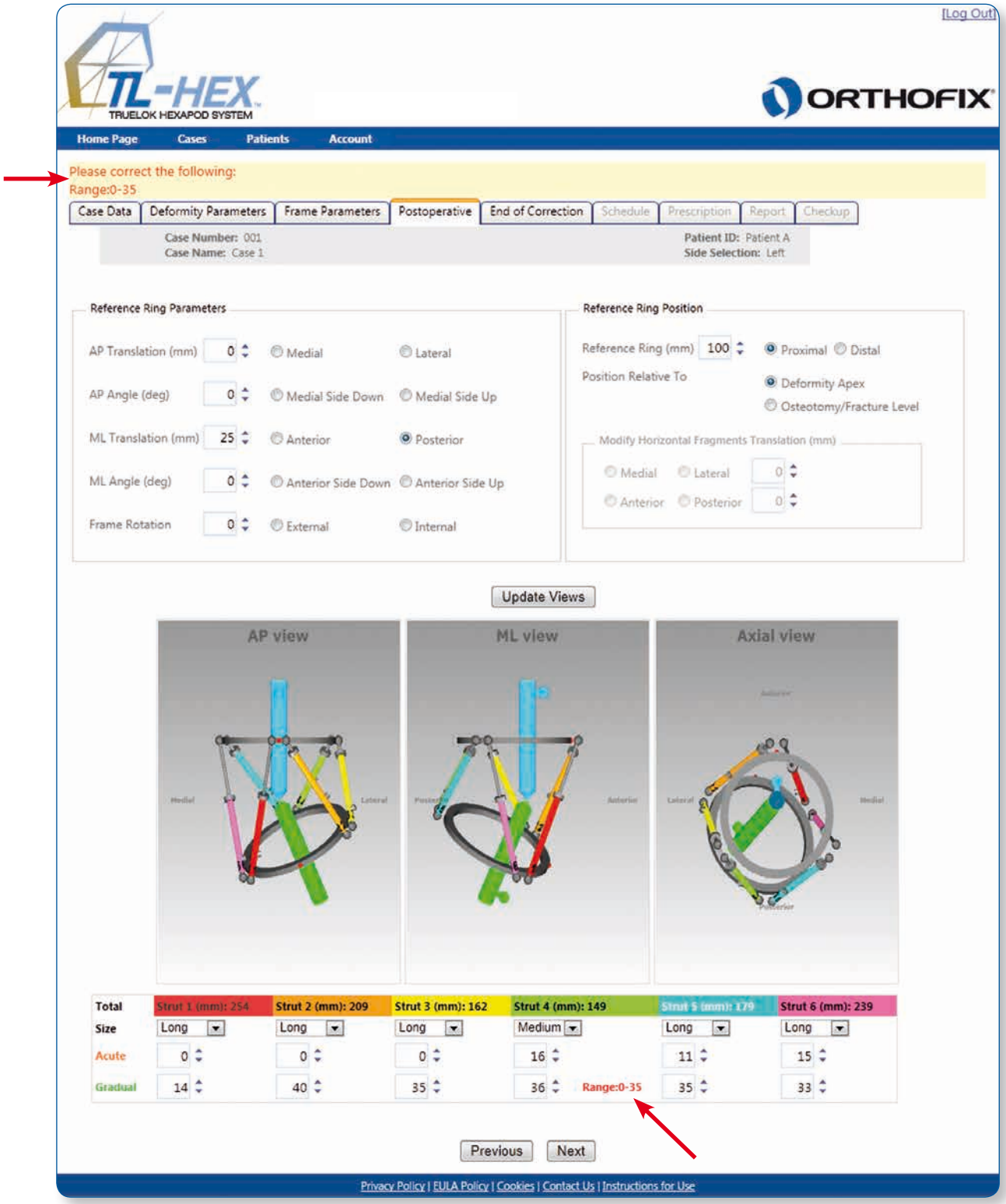


Fig. 23. Updated Postoperative screen, with errors related to incorrect strut lengths.

5.5 End of Correction

The End of Correction screen (Fig. 24) displays the position of the bone segments and the frame at the end of the treatment (deformity correction). The software assumes that, at the end of deformity correction, the bone segments should be in perfect alignment with no limb length discrepancy (amount of lengthening will be equal to the amount of limb length discrepancy value entered at the Deformity Parameters screen). The screen, however, provides the surgeon the opportunity to override the default position as desired. Additional adjustments include: coronal plane (**AP view**) and sagittal plane (**ML view**) angulation and translation and horizontal plane (**axial view**) internal/external rotation. The values entered represent the desired bone segment position at the end of deformity correction. This is useful if an overcorrection or undercorrection is desired at the end of deformity correction (e.g., Blount's deformity correction, where a 10-degree overcorrection is desired).

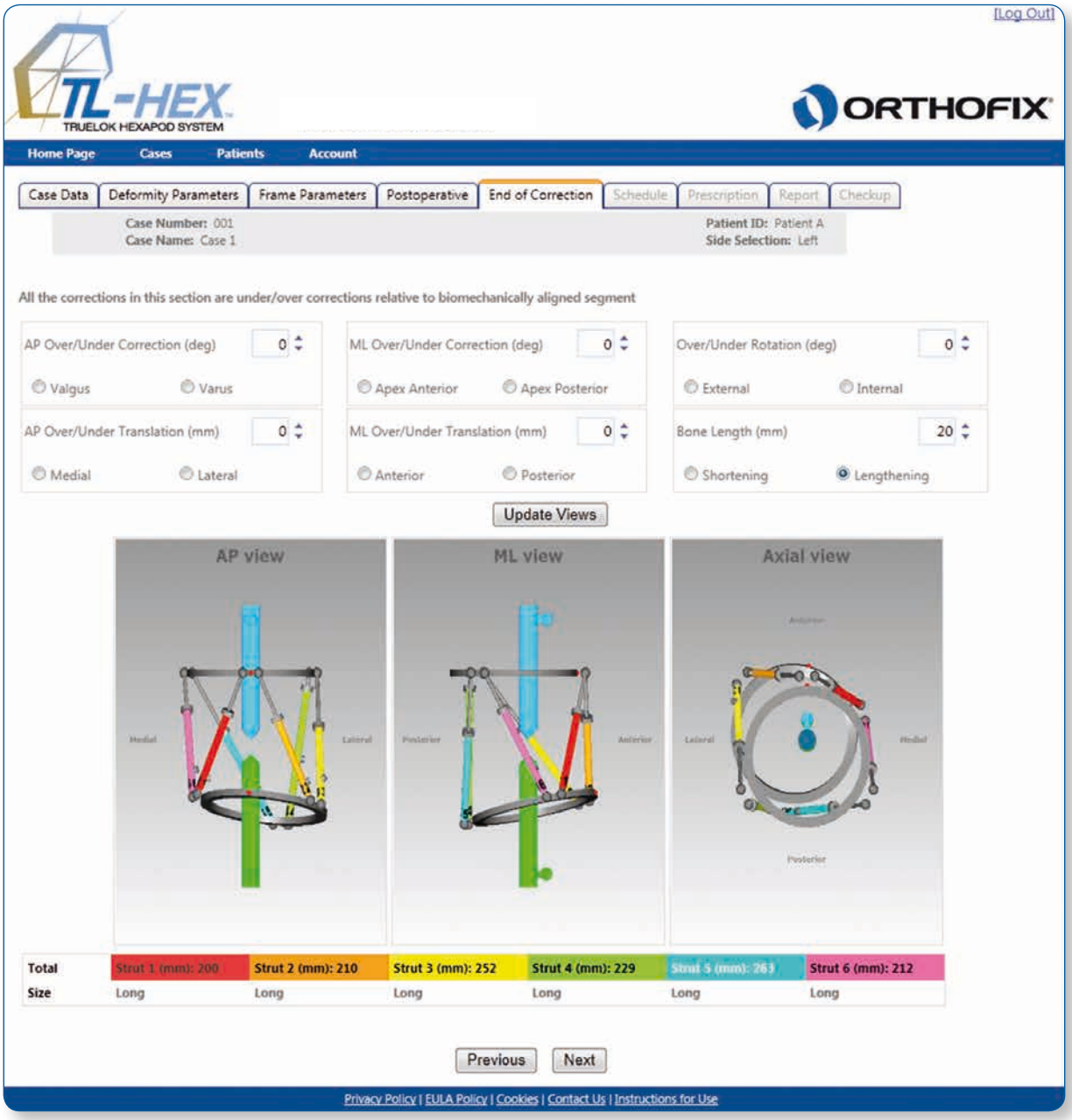


Fig. 24. End of Correction screen.

Click on **Update Views** to check the final struts length.

Note: The Report should be referenced for final strut position (acute and gradual) and strut size.

5.6 Schedule

The Schedule screen (Fig. 25) allows the surgeon to enter or specific parameters related to bone segment movement during the deformity correction. Those parameters include: maximum rate of bone segment translation (Daily Correction Rate in mm/day) , maximum rate of bone segment angular correction (Angular Max Speed in degrees/day), maximum rate of bone segment rotation (Rotate Max Speed in degree/day) and desired days of correction (Days of Correction). Treatment start date may be adjusted using Latency Period (days) and Correction time may be selected in the appropriate box. The correction rates and the days of correction are correlated and, therefore, the surgeon can determine the prescription calculation either choosing a speed parameter or choosing the Days of Correction. Once the "Calculate by" parameter is determined by the surgeon, the other parameters are automatically calculated by the software. It is necessary to enter a values in the "Calculate By" box and "Correction Time(s)" box prior to clicking Calculate.
A warning message will appear if no value was chosen in either of these boxes.

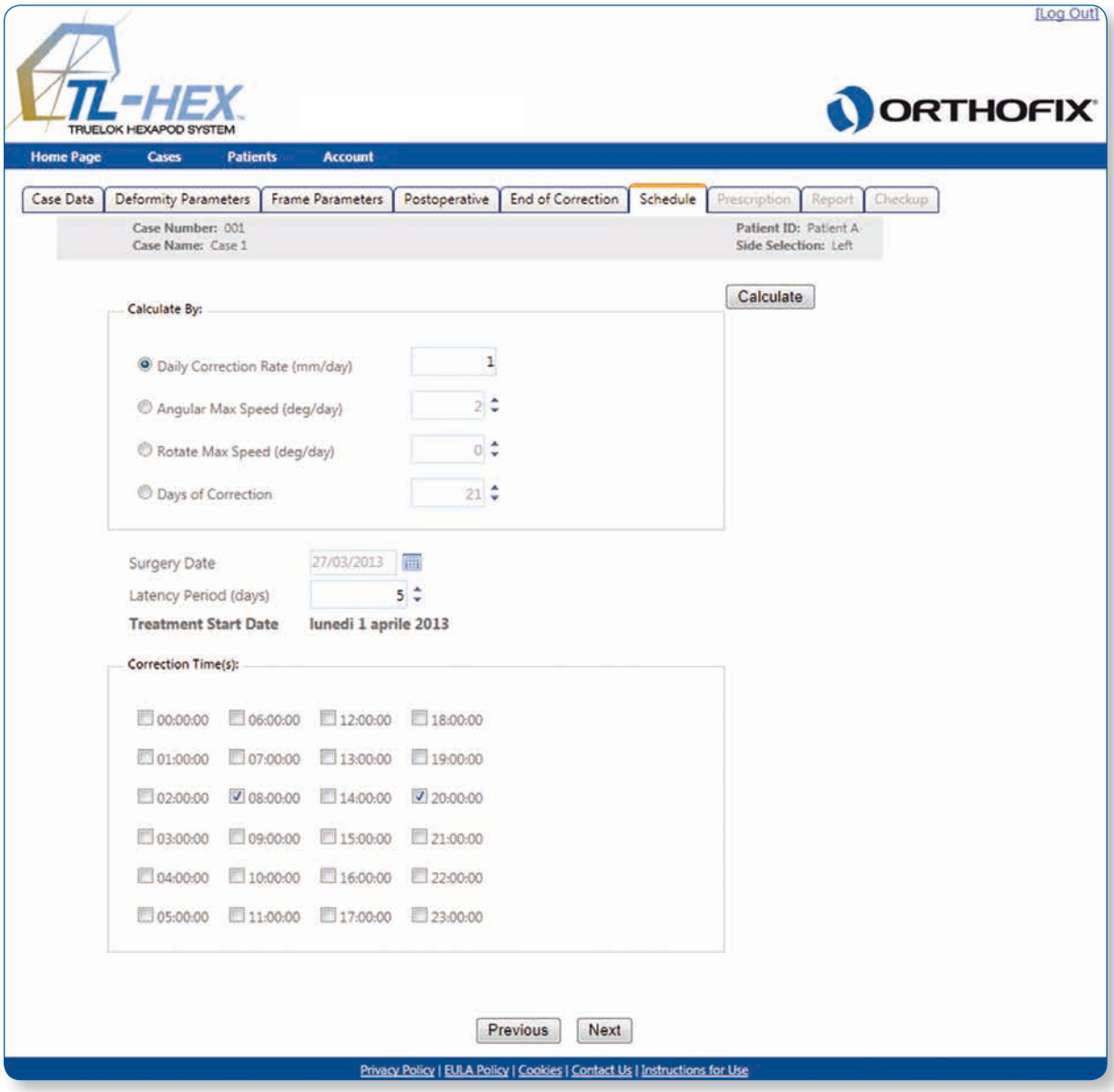


Fig. 25. Schedule screen.

Definitions:
Daily Correction Rate (mm/day) = translation, distraction, compression speed (combination of all the linear speeds).
Angular Max Speed (deg/day) = angular rotation speed (varus-valgus correction)
Rotate Max 5 speed (deg/day) = axial rotation speed (external-internal rotation)

If continuing to the Schedule screen with struts out of range, then once Next is clicked, the surgeon will be advised via a pop-up window that struts are out of range.

5.7 Prescription

The Prescription screen (Fig. 26) displays the adjustment schedule for the patient resulting from the previously entered parameters. Each row in the prescription describes the strut adjustment for the patient to make for each deformity correction step as specified in the schedule. Adjustment for each strut is represented by number of clicks (1/2 rotation of the strut adjustment knob) and can be positive (if strut length increases) or negative (when the strut length decreases). In addition, the gradual adjustment scale value in millimeters is displayed as a reference for each strut.

Note: All information must be reviewed by the surgeon before completing and printing the prescription to ensure that it is accurate.

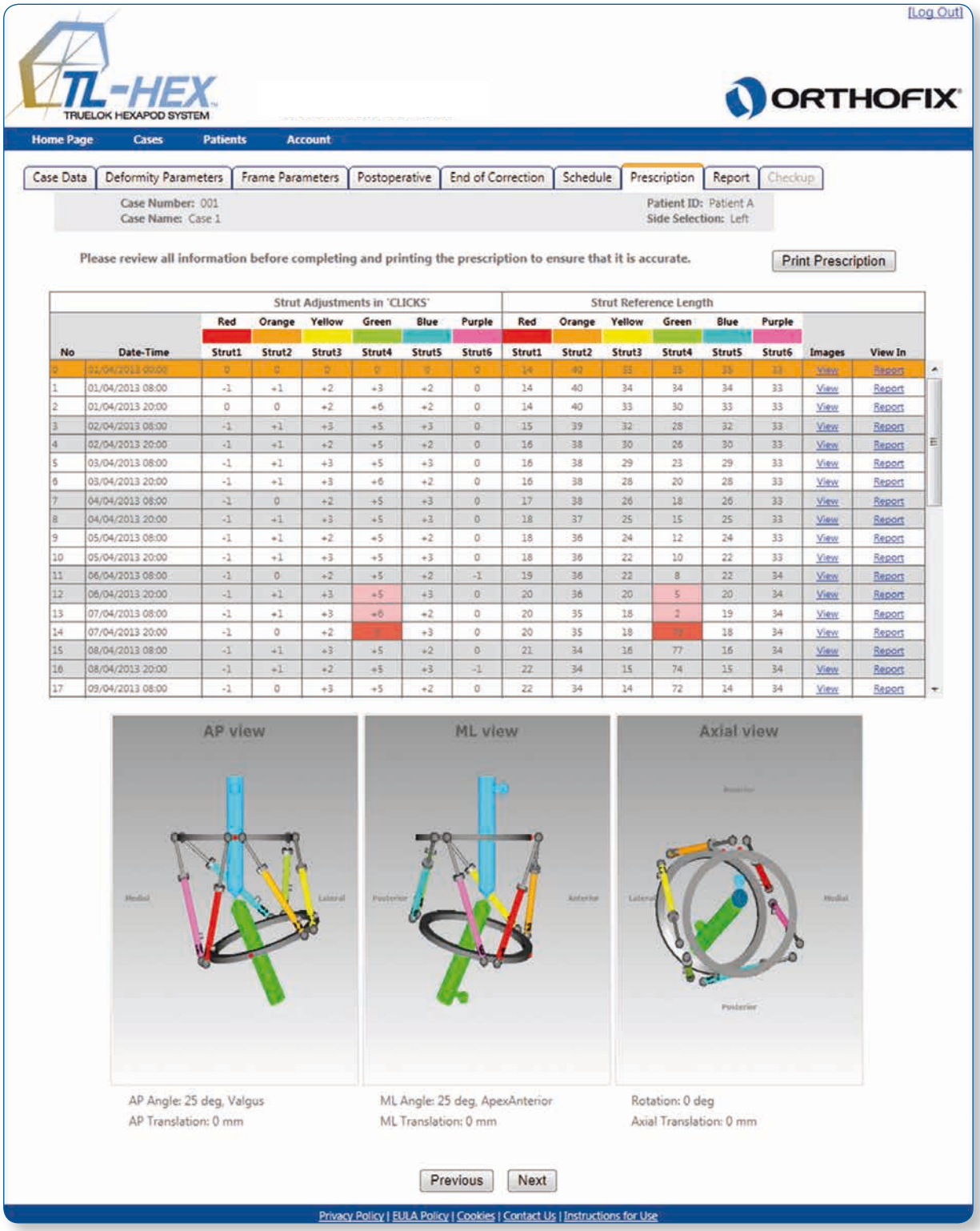


Fig. 26. Prescription screen view before starting the adjustments.

By clicking on **View** in the prescription table, the three views of the deformity and frame will be displayed for the corresponding day/time of the prescription (Fig. 27).

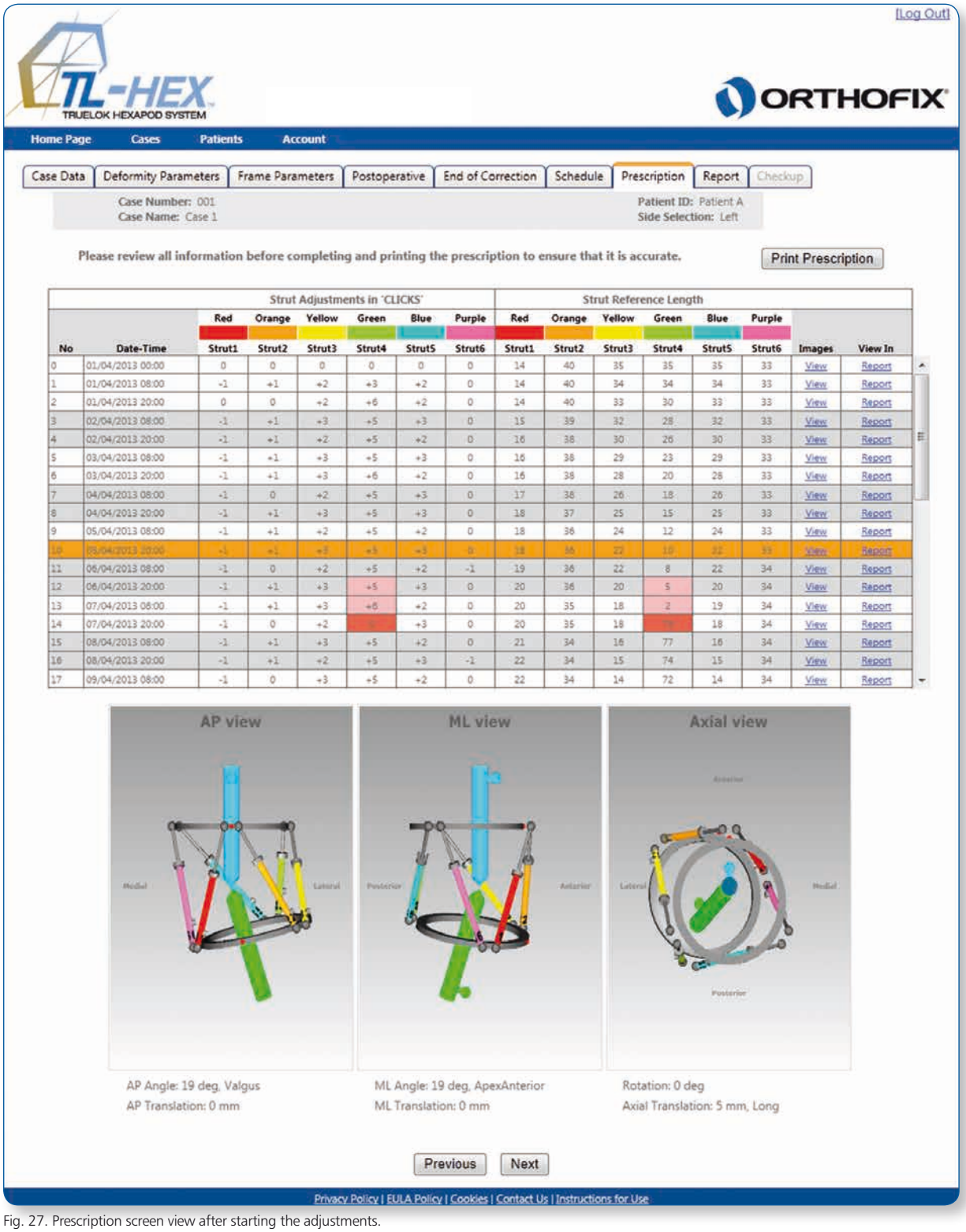
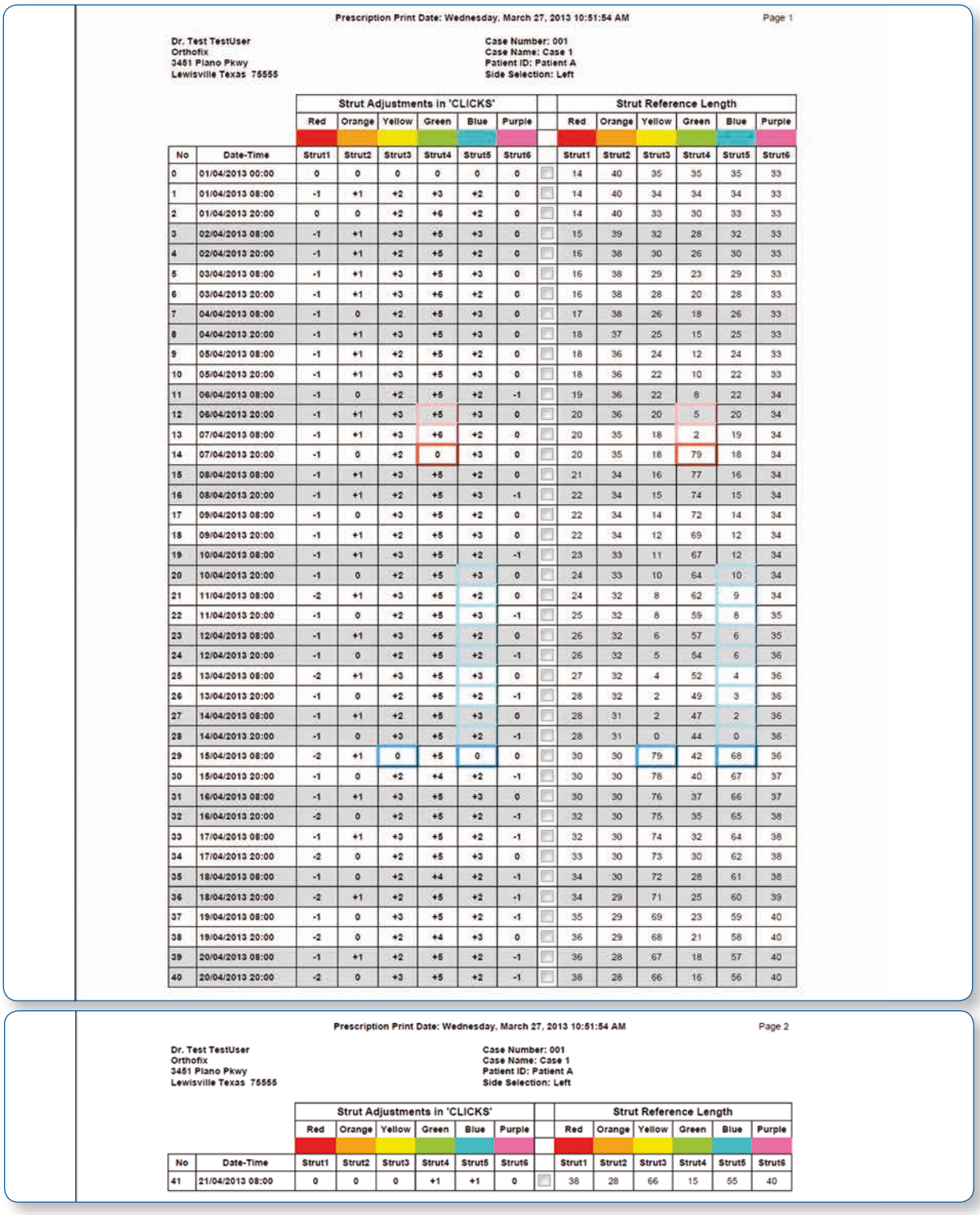


Fig. 27. Prescription screen view after starting the adjustments.

Clicking **Print Prescription** will generate a prescription in PDF format (Fig. 28). This document must then be printed and the hard copy must be issued to the patient and can also be saved for the record. The print-out should be checked for correctness and readability and the patient should be instructed to contact the surgeon in case the prescription becomes lost or damaged.

Note: Please review all information before completing and printing the prescription to ensure that it is accurate.



Prescription Print Date: Wednesday, March 27, 2013 10:51:54 AM Page 1

Dr. Test TestUser
Orthofix
3451 Plano Pkwy
Lewisville Texas 75555

Case Number: 001
Case Name: Case 1
Patient ID: Patient A
Side Selection: Left

		Strut Adjustments in 'CLICKS'							Strut Reference Length					
		Red	Orange	Yellow	Green	Blue	Purple		Red	Orange	Yellow	Green	Blue	Purple
No	Date-Time	Strut1	Strut2	Strut3	Strut4	Strut5	Strut6		Strut1	Strut2	Strut3	Strut4	Strut5	Strut6
0	01/04/2013 00:00	0	0	0	0	0	0		14	40	35	35	35	33
1	01/04/2013 08:00	-1	+1	+2	+3	+2	0		14	40	34	34	34	33
2	01/04/2013 20:00	0	0	+2	+6	+2	0		14	40	33	30	33	33
3	02/04/2013 08:00	-1	+1	+3	+5	+3	0		15	39	32	28	32	33
4	02/04/2013 20:00	-1	+1	+2	+5	+2	0		16	38	30	26	30	33
5	03/04/2013 08:00	-1	+1	+3	+5	+3	0		16	38	29	23	29	33
6	03/04/2013 20:00	-1	+1	+3	+6	+2	0		16	38	28	20	28	33
7	04/04/2013 08:00	-1	0	+2	+5	+3	0		17	38	26	18	26	33
8	04/04/2013 20:00	-1	+1	+3	+5	+3	0		18	37	25	15	25	33
9	05/04/2013 08:00	-1	+1	+2	+5	+2	0		18	36	24	12	24	33
10	05/04/2013 20:00	-1	+1	+3	+5	+3	0		18	36	22	10	22	33
11	06/04/2013 08:00	-1	0	+2	+5	+2	-1		19	36	22	8	22	34
12	06/04/2013 20:00	-1	+1	+3	+5	+3	0		20	36	20	5	20	34
13	07/04/2013 08:00	-1	+1	+3	+6	+2	0		20	35	18	2	19	34
14	07/04/2013 20:00	-1	0	+2	0	+3	0		20	35	18	79	18	34
15	08/04/2013 08:00	-1	+1	+3	+5	+2	0		21	34	16	77	16	34
16	08/04/2013 20:00	-1	+1	+2	+5	+3	-1		22	34	15	74	15	34
17	09/04/2013 08:00	-1	0	+3	+5	+2	0		22	34	14	72	14	34
18	09/04/2013 20:00	-1	+1	+2	+5	+3	0		22	34	12	69	12	34
19	10/04/2013 08:00	-1	+1	+3	+5	+2	-1		23	33	11	67	12	34
20	10/04/2013 20:00	-1	0	+2	+5	+3	0		24	33	10	64	10	34
21	11/04/2013 08:00	-2	+1	+3	+5	+2	0		24	32	8	62	9	34
22	11/04/2013 20:00	-1	0	+2	+5	+3	-1		25	32	8	59	8	35
23	12/04/2013 08:00	-1	+1	+3	+5	+2	0		26	32	6	57	6	35
24	12/04/2013 20:00	-1	0	+2	+5	+2	-1		26	32	5	54	6	36
25	13/04/2013 08:00	-2	+1	+3	+5	+3	0		27	32	4	52	4	36
26	13/04/2013 20:00	-1	0	+2	+5	+2	-1		28	32	2	49	3	36
27	14/04/2013 08:00	-1	+1	+2	+5	+3	0		28	31	2	47	2	36
28	14/04/2013 20:00	-1	0	+3	+5	+2	-1		28	31	0	44	0	36
29	15/04/2013 08:00	-2	+1	0	+5	0	0		30	30	79	42	68	36
30	15/04/2013 20:00	-1	0	+2	+4	+2	-1		30	30	78	40	67	37
31	16/04/2013 08:00	-1	+1	+3	+5	+3	0		30	30	76	37	66	37
32	16/04/2013 20:00	-2	0	+2	+5	+2	-1		32	30	75	35	65	38
33	17/04/2013 08:00	-1	+1	+3	+5	+2	-1		32	30	74	32	64	38
34	17/04/2013 20:00	-2	0	+2	+5	+3	0		33	30	73	30	62	38
35	18/04/2013 08:00	-1	0	+2	+4	+2	-1		34	30	72	28	61	38
36	18/04/2013 20:00	-2	+1	+2	+5	+2	-1		34	29	71	25	60	39
37	19/04/2013 08:00	-1	0	+3	+5	+2	-1		35	29	69	23	59	40
38	19/04/2013 20:00	-2	0	+2	+4	+3	0		36	29	68	21	58	40
39	20/04/2013 08:00	-1	+1	+2	+5	+2	-1		36	28	67	18	57	40
40	20/04/2013 20:00	-2	0	+3	+5	+2	-1		38	28	66	16	56	40

Prescription Print Date: Wednesday, March 27, 2013 10:51:54 AM Page 2

Dr. Test TestUser
Orthofix
3451 Plano Pkwy
Lewisville Texas 75555

Case Number: 001
Case Name: Case 1
Patient ID: Patient A
Side Selection: Left

		Strut Adjustments in 'CLICKS'							Strut Reference Length					
		Red	Orange	Yellow	Green	Blue	Purple		Red	Orange	Yellow	Green	Blue	Purple
No	Date-Time	Strut1	Strut2	Strut3	Strut4	Strut5	Strut6		Strut1	Strut2	Strut3	Strut4	Strut5	Strut6
41	21/04/2013 08:00	0	0	0	+1	+1	0		38	28	66	15	55	40

Fig. 28. Prescription hard copy for the patient.

The direction clips are then applied to the rod end joints according to the prescription. If strut elongation is required (positive numbers in the prescription), the arrow on the clip should point in the same direction as the reference arrow on the adjustment knob (Fig. 29 a). If strut shortening is required (negative numbers in the prescription), the clip should be applied with the arrow pointing in the opposite direction of the arrow on the adjustment knob (Fig. 29 b).

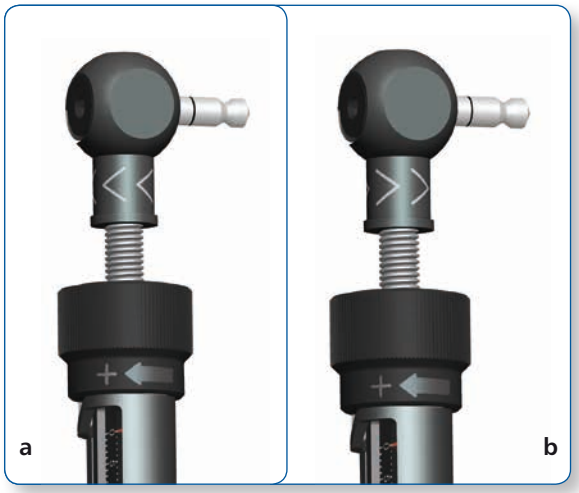


Fig. 29. Orientation of direction clips for strut elongation (a) and shortening (b).

In most of the cases, the orientation of direction clips remains the same throughout the treatment. In some cases with a rotational deformity correction, the direction of strut adjustments in the prescription may change from positive to negative or from negative to positive. In this situation, the surgeon should instruct the patient about the day the change of direction occurs and either schedule a clinic visit for the orientation change of the direction clip or instruct the patient on how to make this orientation change to the direction clip.

In addition, the direction of strut adjustment may change from positive to negative in cases of extreme elongation of the long strut (acute adjustment indicates 80 mm and gradual adjustment indicates 0 mm left on the strut scale) even though additional strut elongation is still required. This situation may occur when external supports are placed too far from each other and maximal elongation of the longest available strut is not enough to achieve the desired amount. The surgeon should review the acute/gradual indication numbers in the Report screen either preoperatively to adjust the ring separation distance or postoperatively to schedule frame modifications on time.

The prescription row will be highlighted when strut readjustment (shaded **blue**) or exchange (shaded **red**) are required (Fig. 30). The rows of lighter shading indicate the allowable range of days that are suitable for the re-adjustment/exchange; the heavier shaded row indicates the last possible day for the strut change.

If the strut re-adjustment/exchange occurs on the last day (marked by the solid color blue/red box), the existent prescription can be used. If the strut readjustment/exchange occurs prior to the last day, a new prescription must be generated from that date. The Checkup screen can be used to create a new case.

The Acute and Gradual values of the new strut, if the exchange /adjustment occurs prior to the last day of possible re-adjustment/exchange, can be found using the conversion tables available online clicking on "Instructions for Use" link on the footer of the www.tlhex.com site.

If strut exchange is required shortly after the beginning of correction and was done before starting the correction, the surgeon should return to the Postoperative screen and move through the End of Correction to re-generate a prescription.

Note: Please review all information before completing and printing the prescription to ensure that it is accurate.

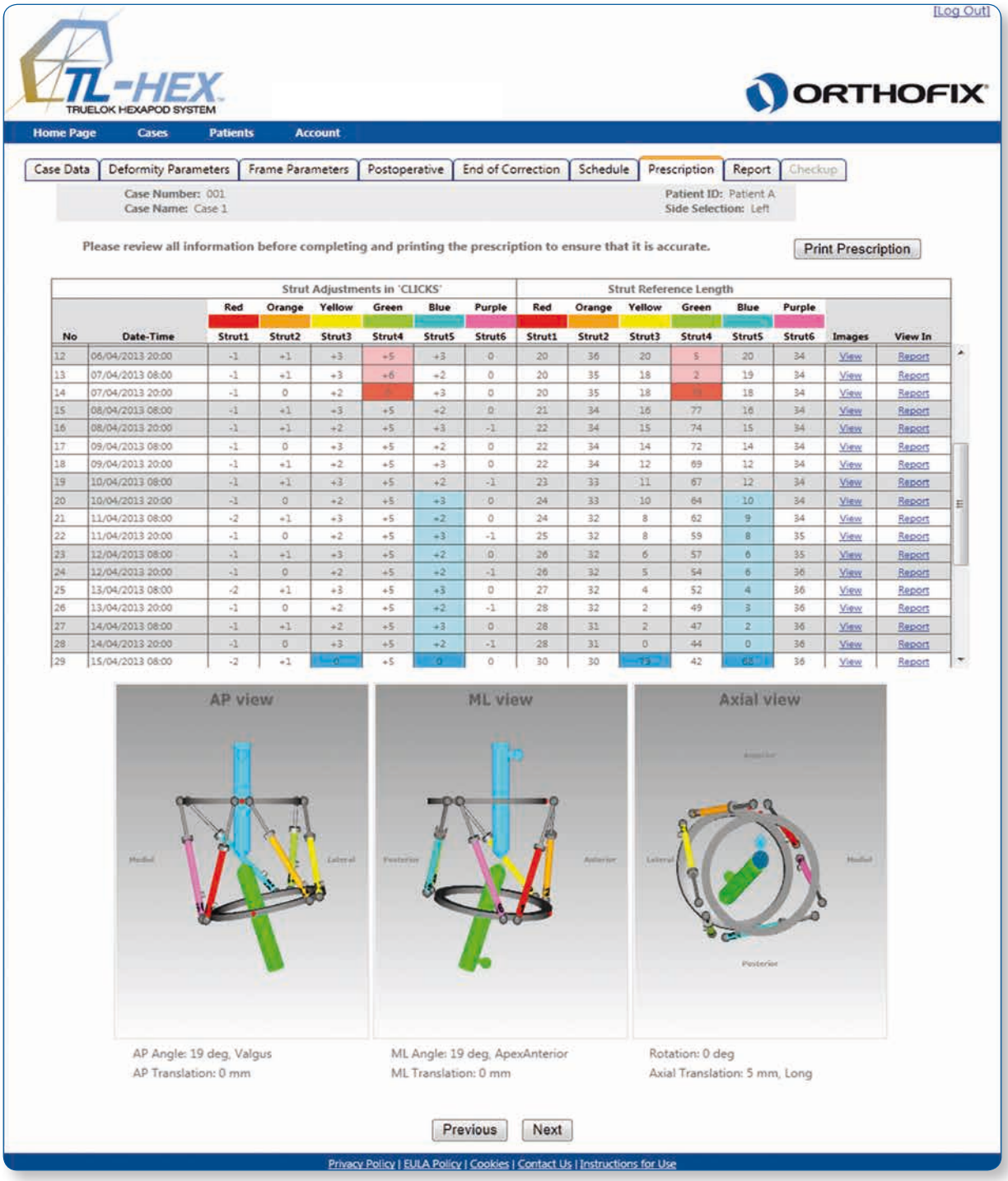


Fig. 30. Prescription screen indicating strut readjustment (blue) and strut exchange (red).

5.8 Report

The Report provides a more detailed prescription for the physician. In addition to the patient prescription, this detailed prescription includes acute and gradual adjustment values in millimeters for each strut (Fig. 31). These values should be checked by the surgeon, especially in cases with extreme compression of the short struts.

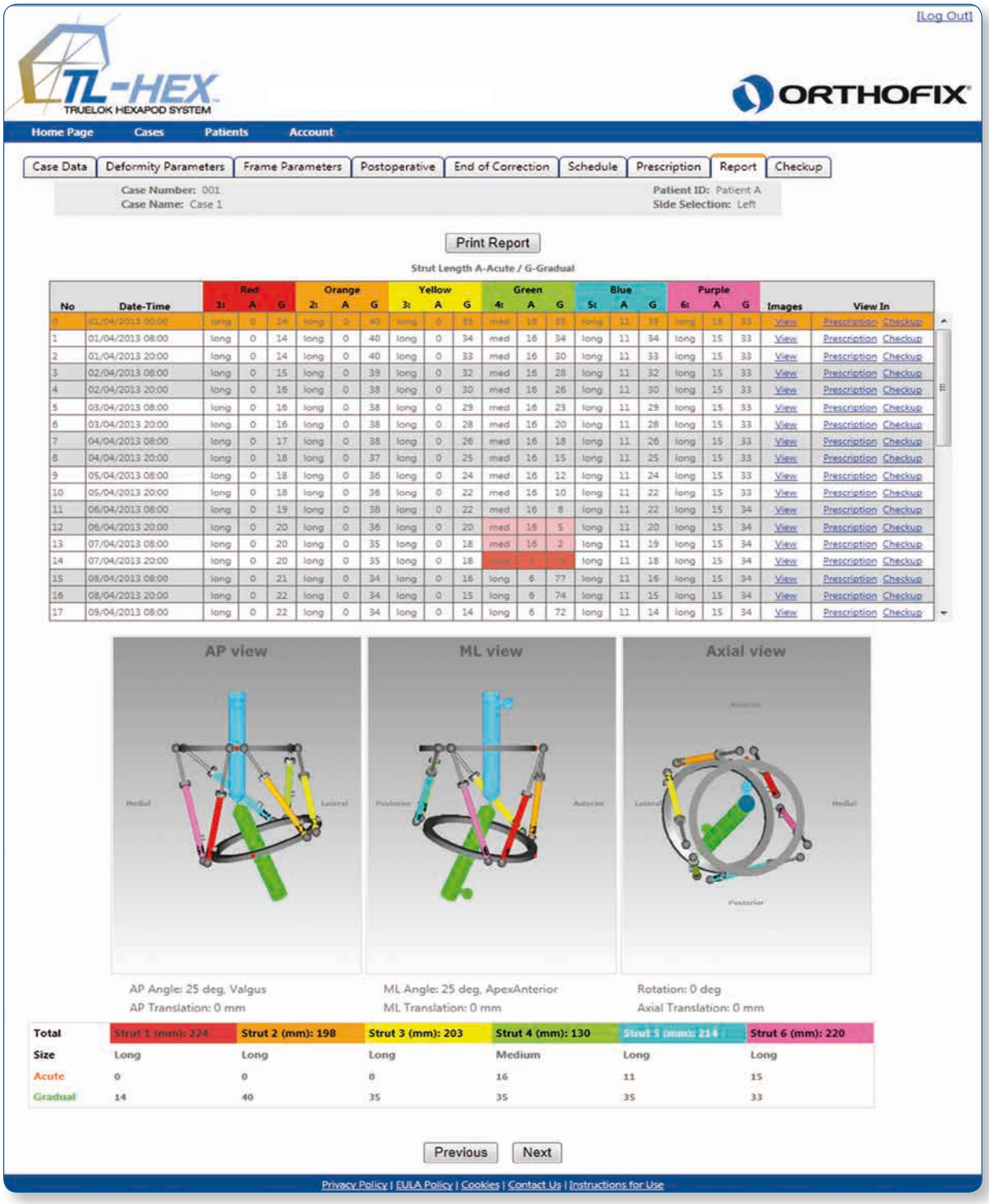


Fig. 31. Report screen view before starting adjustments.

In such a situation when acute adjustment indicates 0 mm and gradual adjustment indicates 15 mm on the strut scale, the external supports were placed too close to each other and maximal shortening of the shortest strut is not enough to achieve the desired amount. If gradual adjustment on the report indicates numbers higher than 15.0 mm, then a frame modification is required to continue compression.

By clicking on the **View** link for any day in the prescription table, the system will generate a view of the bone segments and frame orientation of that particular day as well as the corresponding strut length with Acute/Gradual value (Fig. 32).

By clicking on the Checkup link in the Report table the Checkup screen will be launched for the selected day and time.

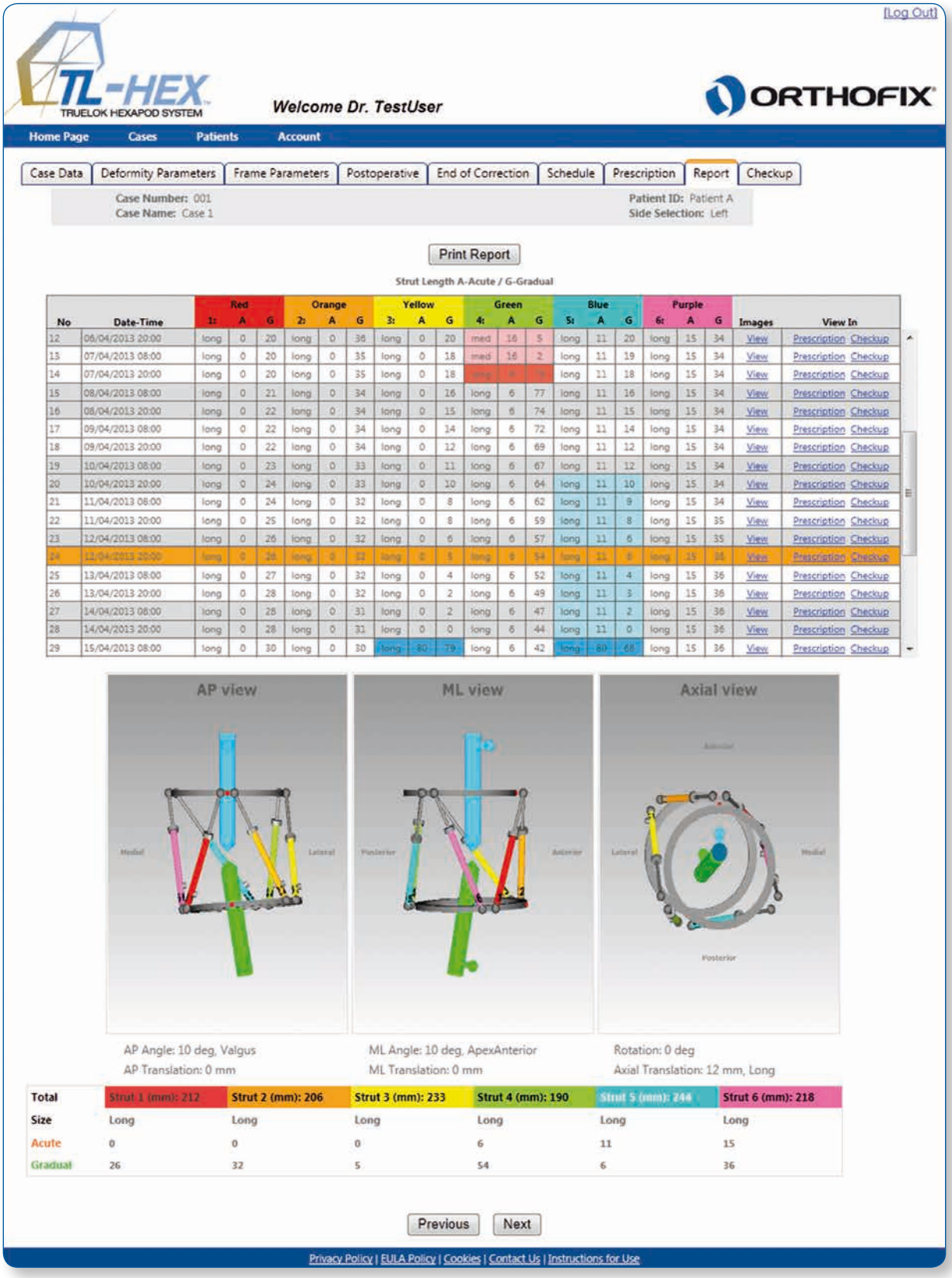


Fig. 32. Report screen view after starting the adjustments.

Similar to Prescription screen, the report row will be highlighted when strut readjustments (shaded **blue**) or exchanges (shaded **red**) are required (Fig. 33). The rows of lighter shading indicate the allowable range of days that are suitable for the readjustment/exchange; the heavier shaded row indicates the last possible day for the readjustment/exchange.

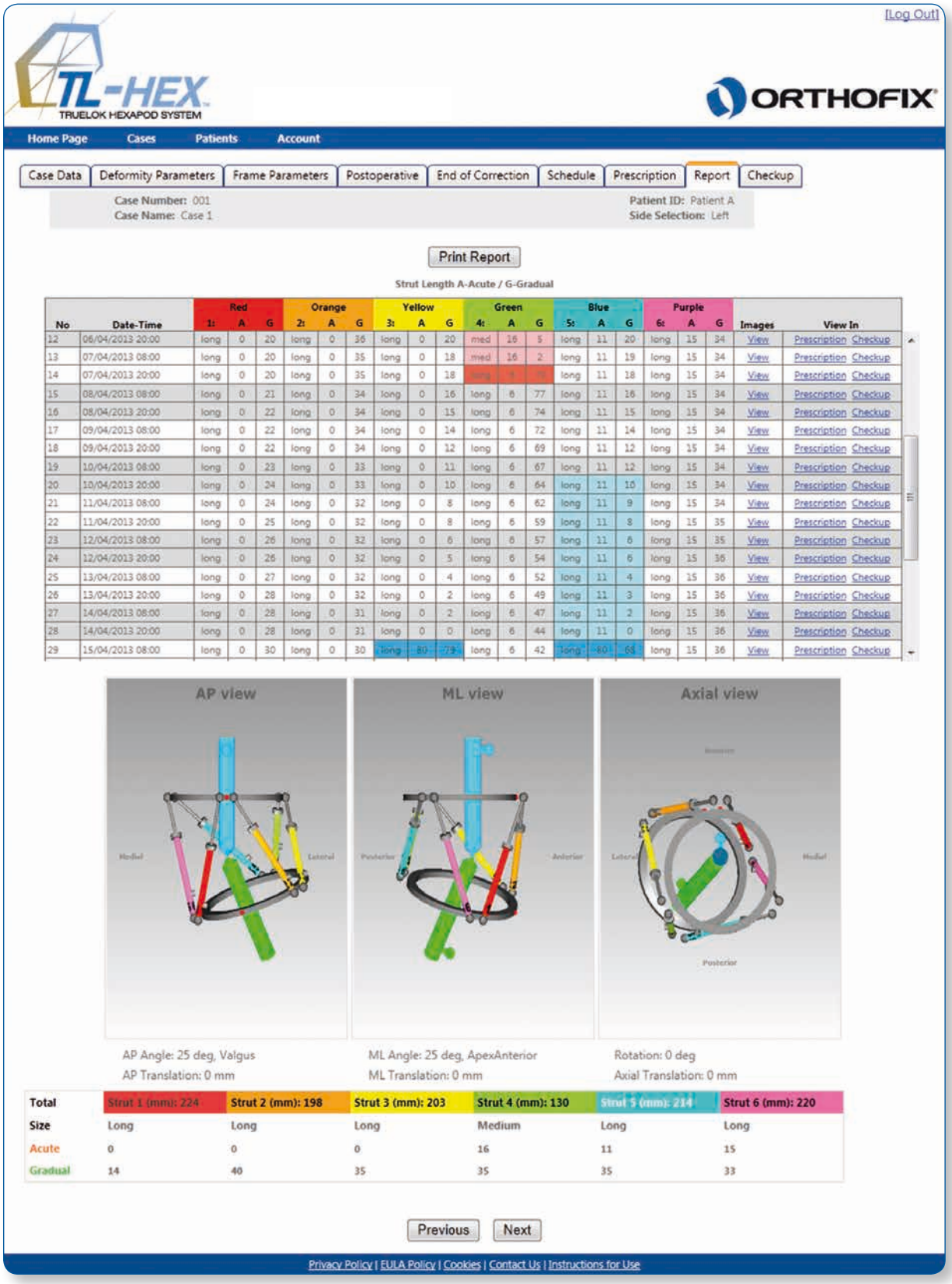


Fig. 33. Report screen indicating strut readjustment (blue) and strut exchange (red).

Clicking **Print Report** will generate a report in PDF format (Fig. 34). This document can be printed and can also be saved for the record.

Case Number: 001
Case Name: Case 1
Patient ID: Patient A
Side Selection: Left

Report Print Date: Wednesday, March 27, 2013 11:07:02 AM
Page 1

		Red			Orange			Yellow			Green			Blue			Purple		
No	Date-Time	1:	A	G	2:	A	G	3:	A	G	4:	A	G	5:	A	G	6:	A	G
0	01/04/2013 00:00	long	0	14	long	0	40	long	0	35	med	16	36	long	11	35	long	15	33
1	01/04/2013 08:00	long	0	14	long	0	40	long	0	34	med	16	34	long	11	34	long	15	33
2	01/04/2013 20:00	long	0	14	long	0	40	long	0	33	med	16	30	long	11	33	long	15	33
3	02/04/2013 08:00	long	0	15	long	0	39	long	0	32	med	16	28	long	11	32	long	15	33
4	02/04/2013 20:00	long	0	16	long	0	38	long	0	30	med	16	26	long	11	30	long	15	33
5	03/04/2013 08:00	long	0	16	long	0	38	long	0	29	med	16	23	long	11	29	long	15	33
6	03/04/2013 20:00	long	0	16	long	0	38	long	0	28	med	16	20	long	11	28	long	15	33
7	04/04/2013 08:00	long	0	17	long	0	38	long	0	26	med	16	18	long	11	26	long	15	33
8	04/04/2013 20:00	long	0	18	long	0	37	long	0	25	med	16	16	long	11	25	long	15	33
9	05/04/2013 08:00	long	0	18	long	0	36	long	0	24	med	16	12	long	11	24	long	15	33
10	05/04/2013 20:00	long	0	18	long	0	36	long	0	22	med	16	10	long	11	22	long	15	33
11	06/04/2013 08:00	long	0	19	long	0	36	long	0	22	med	16	8	long	11	22	long	15	34
12	06/04/2013 20:00	long	0	20	long	0	36	long	0	20	med	16	6	long	11	20	long	15	34
13	07/04/2013 08:00	long	0	20	long	0	35	long	0	18	med	16	2	long	11	19	long	15	34
14	07/04/2013 20:00	long	0	20	long	0	35	long	0	18	long	6	79	long	11	18	long	15	34
15	08/04/2013 08:00	long	0	21	long	0	34	long	0	16	long	6	77	long	11	16	long	15	34
16	08/04/2013 20:00	long	0	22	long	0	34	long	0	15	long	6	74	long	11	15	long	15	34
17	09/04/2013 08:00	long	0	22	long	0	34	long	0	14	long	6	72	long	11	14	long	15	34
18	09/04/2013 20:00	long	0	22	long	0	34	long	0	12	long	6	69	long	11	12	long	15	34
19	10/04/2013 08:00	long	0	23	long	0	33	long	0	11	long	6	67	long	11	12	long	15	34
20	10/04/2013 20:00	long	0	24	long	0	33	long	0	10	long	6	64	long	11	10	long	15	34
21	11/04/2013 08:00	long	0	24	long	0	32	long	0	8	long	6	62	long	11	9	long	15	34
22	11/04/2013 20:00	long	0	25	long	0	32	long	0	8	long	6	59	long	11	8	long	15	35
23	12/04/2013 08:00	long	0	25	long	0	32	long	0	6	long	6	57	long	11	6	long	15	35
24	12/04/2013 20:00	long	0	26	long	0	32	long	0	5	long	6	54	long	11	6	long	15	36
25	13/04/2013 08:00	long	0	27	long	0	32	long	0	4	long	6	52	long	11	4	long	15	36
26	13/04/2013 20:00	long	0	28	long	0	32	long	0	2	long	6	49	long	11	3	long	15	36
27	14/04/2013 08:00	long	0	28	long	0	31	long	0	2	long	6	47	long	11	2	long	15	36
28	14/04/2013 20:00	long	0	29	long	0	31	long	0	0	long	6	44	long	11	0	long	15	36
29	15/04/2013 08:00	long	0	30	long	0	30	long	80	79	long	6	42	long	80	68	long	15	36
30	15/04/2013 20:00	long	0	30	long	0	30	long	80	78	long	6	40	long	80	67	long	15	37
31	16/04/2013 08:00	long	0	30	long	0	30	long	80	76	long	6	37	long	80	66	long	15	37
32	16/04/2013 20:00	long	0	32	long	0	30	long	80	75	long	6	35	long	80	65	long	15	38
33	17/04/2013 08:00	long	0	32	long	0	30	long	80	74	long	6	32	long	80	64	long	15	38
34	17/04/2013 20:00	long	0	33	long	0	30	long	80	73	long	6	30	long	80	62	long	15	38
35	18/04/2013 08:00	long	0	34	long	0	30	long	80	72	long	6	28	long	80	61	long	15	38

Case Number: 001
Case Name: Case 1
Patient ID: Patient A
Side Selection: Left

Report Print Date: Wednesday, March 27, 2013 11:07:02 AM
Page 2

		Red			Orange			Yellow			Green			Blue			Purple		
No	Date-Time	1:	A	G	2:	A	G	3:	A	G	4:	A	G	5:	A	G	6:	A	G
36	18/04/2013 20:00	long	0	34	long	0	29	long	80	71	long	6	25	long	80	60	long	15	39
37	19/04/2013 08:00	long	0	35	long	0	29	long	80	69	long	6	23	long	80	59	long	15	40
38	19/04/2013 20:00	long	0	36	long	0	29	long	80	68	long	6	21	long	80	58	long	15	40
39	20/04/2013 08:00	long	0	36	long	0	28	long	80	67	long	6	18	long	80	57	long	15	40
40	20/04/2013 20:00	long	0	38	long	0	28	long	80	66	long	6	16	long	80	56	long	15	40
41	21/04/2013 08:00	long	0	38	long	0	28	long	80	66	long	6	15	long	80	55	long	15	40

Fig. 34. Printed copy of the report.

5.9 Checkup

The Checkup screen (Fig. 35) provides the position of the bone segments and the frame with corresponding strut adjustment values at any particular day of treatment (deformity correction). When the Checkup screen is opened, it defaults to the Treatment Start Date or the treatment date from which the Checkup has been launched from the Report Screen. If necessary, use the Calendar to select the date the new case should begin. Click Create New Case and a new case will be generated using the parameters of the bone segment position and the strut length values (from the date selected) as starting point. The Create New Case screen is used in the following situations:

- Changes in parameters of strut adjustment
- Unplanned strut readjustment or exchange
- Residual correction is required
- Next treatment phase for the staged correction

Before clicking on Create New Case the new case number and new case name can be entered into the corresponding fields. Clicking on Create New Case will open Case Data screen for the newly generated case. All the deformity and frame parameters will be transferred from the previous case at the date of check-up.

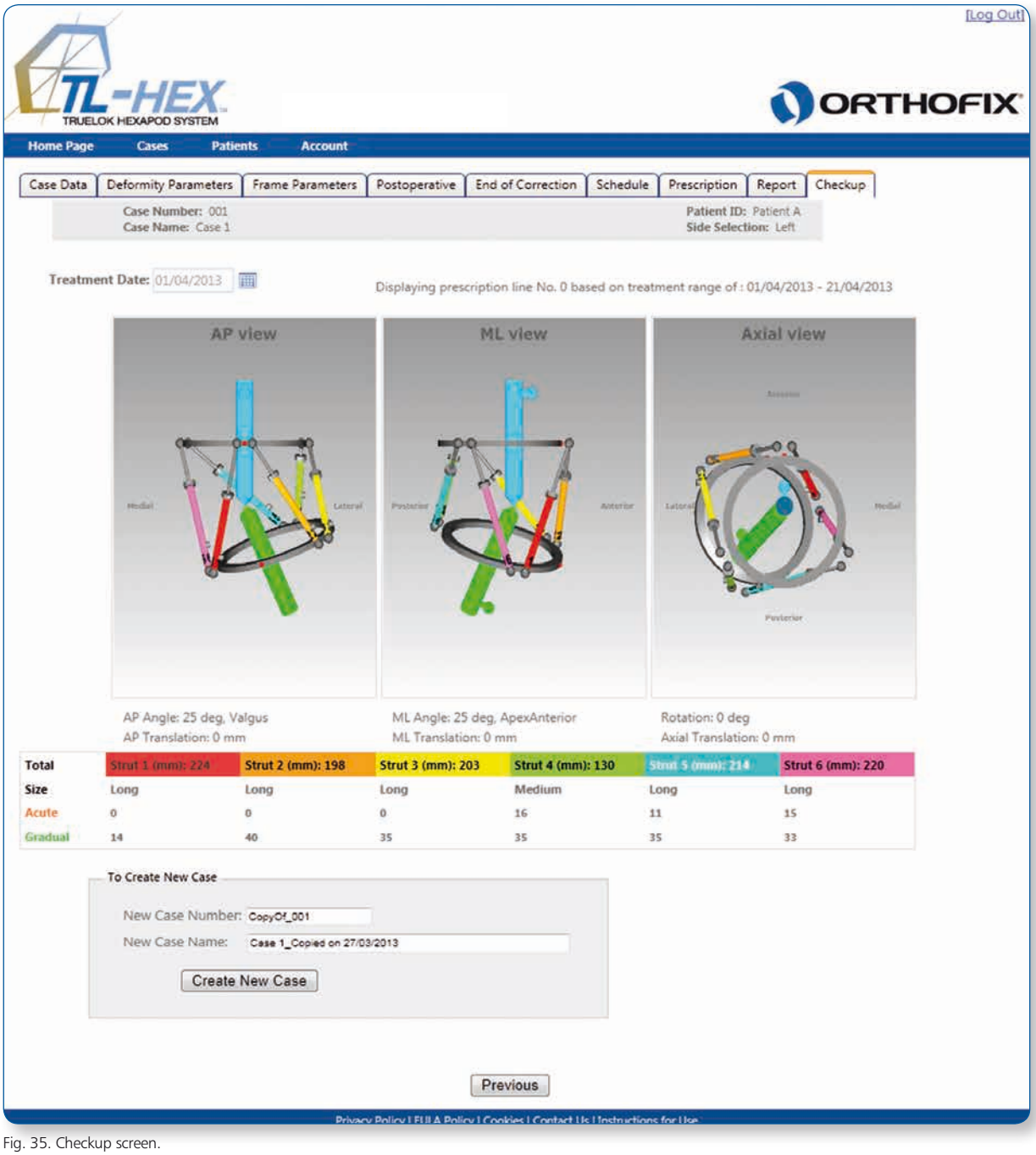


Fig. 35. Checkup screen.

The standard software steps are now followed to complete the new planning from this starting point (Fig. 36). The surgeon should check and adjust Deformity Parameters if necessary (Fig. 37). The Frame Parameters section should be skipped and the surgeon should proceed to the Postoperative section where mounting parameters and strut parameters should be verified and adjusted if necessary. This will result in a new prescription for the patient, based on the starting point as chosen from the Checkup screen.

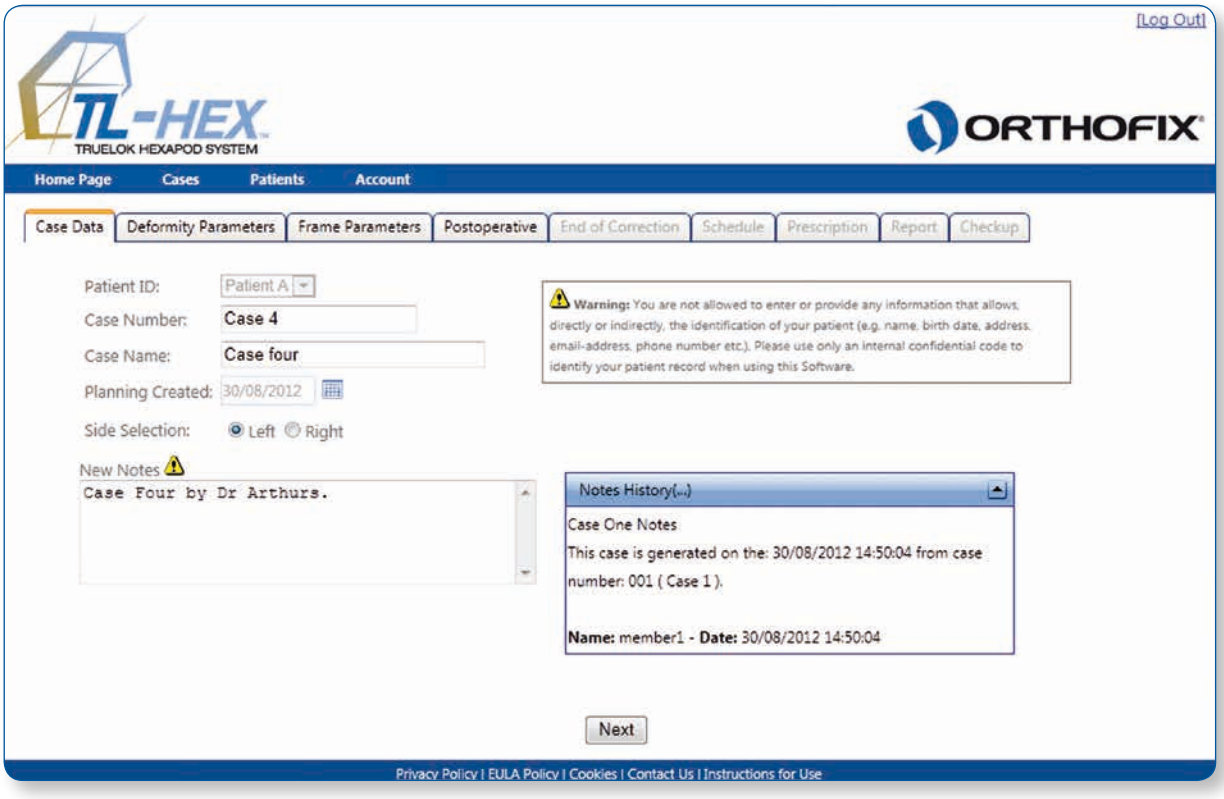


Fig. 36. Create New Case screen.

Note: The surgeon should verify and if needed, re-enter the parameters (bone length or over/under correction).

Fig. 37. Verify deformity parameters.

6. Website Navigation

- In general, it is good practice to click the Update Views after making any changes to the on screen parameters. This will provide visual confirmation that the changes are as intended.
- Regardless of whether the Update Views is clicked after changing one or more parameters, the new parameters will be saved once either Next or one of the function tabs are clicked.
- When a new case is initiated, the flow is from left to right. For example, the user begins with the **Case Data** tab, followed by **Deformity Parameters** tab, etc. Tabs that are not appropriate to the next step of the case planning process are grayed out. Once the case is completed, the user can navigate freely between tabs.
- The TL-HEX software is designed for minimal response (wait) time. However, in the event of Internet transmission delays, an "in process" spinner wheel is displayed while the user's PC is waiting for a response from the TL-HEX server (Fig. 38).
- In certain situations (such as a ring size change), recalculation of the strut lengths is required. In these situations, the popup window appears on the screen (Fig. 39).
- In case of temporary loss of Internet connection and/or when done for the day (by logging off), the surgeon should close the Internet Browser, then reopen browser, clear the browser history, open TL-HEX application and login.
- The session will automatically time out after 30 minutes. The surgeon should close the Internet Browser, then reopen browser, clear the browser history, open TL-HEX application and login.

Fig. 38. "In process" spinner.

Fig. 39. Popup window for calculation of strut lengths.

6.1 Change Password

It is recommended that the user change the password during the first login and periodically thereafter. The Change Password screen (Fig. 40) appears by clicking on the **Account** menu. Simply enter the current password, followed by entering and confirming the new password, then click Change Password. Passwords must be 6 or more characters and is case sensitive.

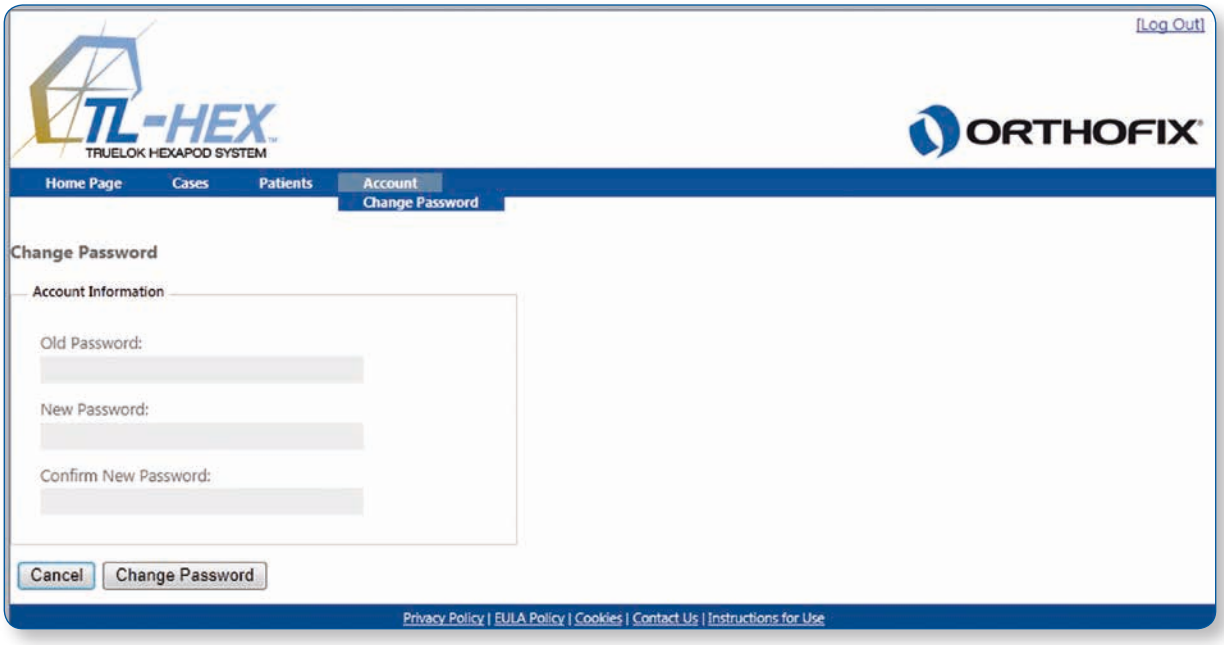


Fig. 40. Change Password screen.

It is important to remember that the surgeon remains ultimately responsible for the confidentiality of the information entered into the software. One of the ways to ensure confidentiality is to ensure password integrity by changing it at regular intervals and by keeping the password as secure as possible.

Warning: Under the Orthofix Terms of Use (End User License Agreement and Privacy Policy), the surgeon should never enter information that directly identifies a patient. The patient number is intended to be used as an identifying link to the patient within the surgeon's patient management system.

For technical support or information on Software Use please contact the Customer Care: **tlhexcustomercare@orthofix.com**
For further support contact info and resources refer to **www.tlhex.com**

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